

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), (b) (7) Investigator
Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property
Owner (b) (6), (b) (7)(C), (b) (4)
Other _____

3. Location where property was acquired
(b) (6), (b) (7)(C), (b) (4) CA

4. Date of acquisition: 09/12/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.
OR130018BR-301 1 envelope 30 seeds of Express wheat

7. Initiating official should appear as first person relinquishing item.

Item No. Relinquished by (b) (6), (b) (7)(C) Received By Date
OR130018BR Sign and Print Name
301 (b) (6), (b) (7)(C) 9/13/13 (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C) Investigator Daren R See 9-13-13

Item No. Relinquished by Date Received By Date
Sign and Print Name Sign and Print Name

Item No. Relinquished by Date Received By Date
Sign and Print Name Sign and Print Name

Item No. Relinquished by Date Received By Date
Sign and Print Name Sign and Print Name

Item No. Relinquished by Date Received By Date
Sign and Print Name Sign and Print Name

Item No. Relinquished by Date Received By Date
Sign and Print Name Sign and Print Name

Item No. Relinquished by Date Received By Date
Sign and Print Name Sign and Print Name

Control number or name _____

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OR120018_BR_002875

T69 Chain of Custody (2-08)



United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), (b) (7)(C) Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property
Owner (b) (6), (b) (7)(C), (b) (6)
Other

3. Location where property was acquired
(b) (6), (b) (7)(C), (b) (4) CA

4. Date of acquisition: 09/12/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.

OR130018BR-300 1 envelope 43 seeds of Madsen wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by	Date	Received By	Date
OR130018BR-300	Sig (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) Investigator	9/13/13	Sig and Print Name (b) (6), (b) (7)(C) Jesse B. See	9-13-13

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

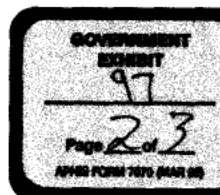
Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Control number or name

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OR120018_BR_002877

T69 Chain of Custody (2-08)



United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Issuing Official and Title
(b) (6), (b) (7)(C)
Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property

Owner (b) (6), (b) (7)(C), (b) (4)
Other

3. Location where property was acquired

(b) (6), (b) (7)(C), (b) (4) (b) (6)

4. Date of acquisition: 09/12/13

5. Purpose for which obtained: Research

6. Item No.	Quantity	Description of Articles
OR130018BR-301	1 envelope	21 seeds of Avocets wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018BR-301	(b) (6), (b) (7)(C) Investigator	9/13/13	(b) (6), (b) (7)(C) Steven B. See	9-13-13

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Control number or name

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T69 Chain of Custody (2-08)



Declaration of (b)(6), (b)(7)(C)

I declare that my name is (b)(6), (b)(7)(C) am over the age of eighteen and I am fully competent to make this declaration. I know each of the facts set forth herein to be true based on personal firsthand knowledge:

I am currently employed as a Senior Investigator with the United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS), Investigative and Enforcement Services (IES). I have been employed in this position for approximately (b)(6), (b)(7)(C) years. My business address is USDA, APHIS, IES, 2150 Centre Avenue, Bldg. (b)(6), (b)(7)(C) Fort Collins, CO 80526. My office telephone number is (b)(6), (b)(7) and my cell phone number is (b)(6), (b)(7)(C).

On 11/13/13, I met with (b)(6), (b)(7)(C), (b)(4), (b)(6), (b)(7)(C) (b)(6), (b)(7)(C). His contact information is (b)(6), (b)(7) (phone), (b)(6), (b)(7)(C) e-mail), and (b)(6), (b)(7)(C) (web site). Also present during the interview was Sharon M. Talley, Ph.D. Biological Scientist, Western Compliance Assurance Branch USDA - APHIS - BRS (Dr. Talley). Dr. Talley accompanied me to this meeting as a subject matter expert (SME) in plant genetics and the molecular makeup in wheat.

The purpose of my contacting (b)(6), (b)(7)(C) was to obtain information from him regarding his work and or involvement with research conducted by him in the (b)(6), (b)(7)(C). I requested (b)(6), (b)(7)(C) explain to Dr. Talley how and why he (b)(6), (b)(7)(C). We also asked (b)(6), (b)(7)(C) if he had any of the filial generations of Express, Madsen or Avocet during his (b)(6), (b)(7)(C) Express, Madsen and Avocet were the wheat varieties used to (b)(6), (b)(7)(C).

I asked (b)(6), (b)(7)(C) to explain the process for (b)(6), (b)(7)(C). He said (b)(6), (b)(7)(C) he received the germplasm of (b)(6), (b)(7)(C), which has a gene that is (b)(6), (b)(7)(C). He then made individual selections of the offspring for the (b)(6), (b)(7)(C). He then took those offspring (b)(6), (b)(7)(C) and made individual selection for the (b)(6), (b)(7)(C). He continued to do this individual selection (b)(6), (b)(7)(C). He did the same thing with crossing (b)(6), (b)(7)(C). He then made individual selections of the offspring for the (b)(6), (b)(7)(C) trait. He then took those offspring and (b)(6), (b)(7)(C) and made individual selection for the (b)(6), (b)(7)(C).

(b)(6), (b)(7)(C) He did this (b)(6), (b)(7)(C) (C)
After he had (b)(6), (b)(7)(C) he then took those two crosses and bred them together for (b)(6), (b)(7)(C) With each generation he would individually select plants which had both of the (b)(6), (b)(7)(C) traits and crossed those plants. He continued this process for (b)(6), (b)(7)(C) (b)(6), (b)(7)(C) in the plant. When he had this completed, the end product was (b)(6), (b)(7)(C) (b)(6), (b)(7)(C) sent the final product to (b)(6), (b)(7)(C) in Arizona.

(b)(6), (b)(7)(C) said it would be easy to determine if what we are looking at (from the Oregon field) is (b)(6), (b)(7)(C) All you would have to do is look for the (b)(6), (b)(7)(C) markers in the plants. If both of these markers are not in the plant then it can not be (b)(6), (b)(7)(C) It must be something else. (C)

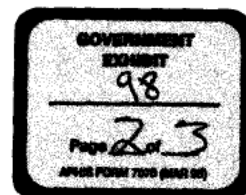
I asked him if he sent each generation of the seed sample to WestBred. (b)(6), (b)(7)(C) said he sent seeds from all generations of the (b)(6), (b)(7)(C) trial to (b)(6), (b)(7)(C) of (b)(6), (b)(7)(C), AZ. He said he does not know the exact dates when he did this but said he sent the seeds as soon as he had the seed. He went on to say he does not know what WestBred did with the seed. It is of no concern to him as it is their product and they can do with it as they see fit. He never asked what they were doing with the seed.

When asked if we could obtain seed samples from this research he stated he thought we already had the seed, from when I had visited with him in September. I explained the only seed which had been provided were samples from the "parents" (b)(6), (b)(7)(C) (b)(6), (b)(7)(C) when he originally started the (b)(6), (b)(7)(C) We did not receive any of the generational seed samples. (b)(6), (b)(7)(C) said if he had any seed and we felt it would be helpful, he is willing to give us what we want. He said he does not think there is anything, which would be helpful but if we want it, we are more than welcome to it. I asked (b)(6), (b)(7)(C) if he wanted to know why we were requesting the seed. He said no, it is none of his business and he does not want to get involved. (C)

We asked (b)(6), (b)(7)(C) when he started working to develop (b)(6), (b)(7)(C) He got on his computer and printed out a sheet entitled (b)(6), (b)(7)(C) Looking at the paper it appears the development of (b)(6), (b)(7)(C) and the original (b)(6), (b)(7)(C)

(b)(6), (b)(7)(C) had his (b)(6), (b)(7)(C), look through their seed freezer for any generations of the (b)(6), (b)(7)(C) We thanked (b)(6), (b)(7)(C) for his time and explaining the process of his work. (C)

Later in the day, (b)(6), (b)(7)(C) called and told me she found samples in their freezer and would



have them ready for pick up in the A.M. on 11/14/13.

On 11/14/13, Dr. Talley and I went back to (b)(6), (b) and collected 12 envelopes of seed from (b)(6), (b). I had carried and delivered these seeds to Dr. See at WSU in Pullman, WA on 11/16/13. I issued a chain-of-custody for each envelope of seed:

- 1) OR130018-BR-351 contained 5 seeds of 04660/2 Express Yr15 2ns BC6 F4 wheat
- 2) OR130018-BR-352 contained 28 seeds of 04660/8 Express Yr15 2ns BC6 F4 wheat
- 3) OR130018-BR-353 contained 4 seeds of 04660/9 Express Yr15 2ns BC6 F4 wheat
- 4) OR130018-BR-354 contained 17 seeds of 04660/17 Express Yr15 Lr37 BC6 F4 wheat
- 5) OR130018-BR-355 contained 6 seeds of 04660/25 Express Yr15 2ns BC6 F4 wheat
- 6) OR130018-BR-356 contained 6 seeds of 04660/29 Express Yr15 2ns BC6 F4 wheat
- 7) OR130018-BR-357 contained 96 seeds of 03674/8 Express Homo Yr15 Het 2ns BC6 F3 wheat
- 8) OR130018-BR-358 contained 43 seeds of 03674/11 Express Homo Yr15 Het 2ns BC6 F3 wheat
- 9) OR130018-BR-359 contained 6 seeds of 00683/5 X Express BC4 wheat
- 10) OR130018-BR-360 contained 10 seeds of 00675/1 X Express BC3 wheat
- 11) OR130018-BR-361 contained 11 seeds of 99659/5 X Express BC2 wheat
- OR130018-BR-362 contained 9 seeds of 98629/2 X Express BC1 wheat

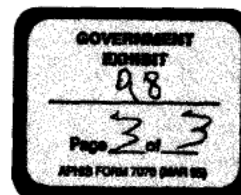
Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. This declaration was executed on September 20, 2013.

(b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

Investigator

USDA-APHIS-IES



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United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), (b) (7)(C) - Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property

Owner

Other

3. Location where property was acquired

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item

No.

Quantity

Description of Articles
Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.

OR130018BR-351 1 envelope 5 seeds of 04660/2 Express yr15 2ns RC6 F4 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018BR-351	(b) (6), (b) (7)(C)	11/16/13	Deven R. Jec	11-16-13
	(b) (6), (b) (7)(C)			

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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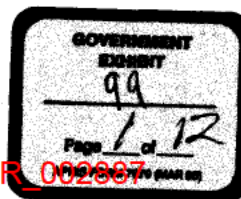
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Control number or name

Page 1



T69 Chain of Custody (2-08)

OR120018_BR_002887

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property

Owner (b) (6), (b) (7)(C)
Other

3. Location where property was acquired

(b) (6), (b) (7)(C)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item

Description of Articles

No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.

OR130018BR-352 1 envelope 28 seeds of 04660/8 Express yr15 2ns BC6 F4 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by	Date	Received By	Date
OR130018BR-352	(b) (6), (b) (7)(C)	11/16/13	Devin R. Sec	11-16-13

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

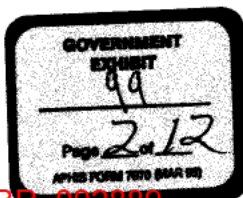
Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Control number or name

Page 1



T69 Chain of Custody (2-08)

OR120018_BR_002889

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title (b)(6), (b)(7)(C) Investigator		Receiver's Office and Location Helena, MT
2. Full Name and Address of Person furnishing property Owner (b)(6), (b)(7)(C) Other		3. Location where property was acquired (b)(6), (b)(7)
		4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item No.	Quantity	Description of Articles
		Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.
OR130018BR-353	1 envelope 4 seeds of 04660/9 Express vrl5 2ns BC6 F4 wheat	

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by	Date	Received By	Date
OR130018BR-353	(b)(6), (b)(7)(C)	11/16/13	Heaven R See	11-16-13

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Control number or name _____

Page 1

OR120018 BR 002391



T69 Chain of Custody (2-08)

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), (b) (7) Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property
Owner (b) (6), (b) (7)(C)
Other

3. Location where property was acquired
(b) (6), (b) (7)(C) (b) (6), (b) (7)(C)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.
OR130018BR-354 1 envelope 17 seeds of 04660/17 Express Vr15 Lr37 BC6 F4 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by	Date	Received By	Date
OR130018BR-354	(b) (6), (b) (7)(C)	11/16/13	Deven R. See	11-16-13
	(b) (6), (b) (7)(C)			

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Control number or name

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OR120018 BR 002893



T69 Chain of Custody (2-08)

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property
Owner (b) (6), (b) (7)(C)
Other

3. Location where property was acquired
(b) (6), (b) (7)(C)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.

OR130018BR-355 1 envelope 6 seeds of 04660/25 Express vrl5 2ns BC6 F4 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by	Date	Received By	Date
OR130018BR-355	(b) (6), (b) (7)(C)	11/13	Deven R. Lee	11-16-13
	(b) (6), (b) (7)(C)		(b) (6), (b) (7)(C)	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

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	Sign and Print Name		Sign and Print Name	

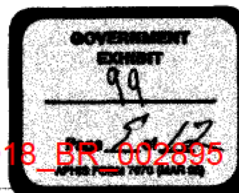
Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Control number or name

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OR120018 BR 002895



T69 Chain of Custody (2-08)

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title (b)(6), (b)(7)(C) Investigator	Receiver's Office and Location Helena, MT
2. Full Name and Address of Person furnishing property Owner (b)(6), (b)(7)(C) Other	3. Location where property was acquired (b)(6), (b)(7)(C) (b)(6), (b)(7)(C)
	4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item No.	Quantity	Description of Articles
OR130018BR-356	1 envelope	6 seeds of 04660/29 Express yr15 2ns BC6 F4 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018BR-356	(b)(6), (b)(7)(C)	11/16/13	Deven R. See (b)(6), (b)(7)(C)	11-16-13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date

Control number or name

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OR120018 BR 002897



T69 Chain of Custody (2-08)

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), (b) Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property
Owner (b) (6), (b) (7)(C)
Other

3. Location where property was acquired
(b) (6), (b) (7) (b) (6)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.
OR130018BR-357 1 envelope 96 seeds of 03674/8 Express Homo yr15 Hat Zns BC6 F3 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018BR-357	(b) (6), (b) (7)(C) Investigator	11/16/13	Debra R. See (b) (6), (b) (7)(C)	11-16-13

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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OR120018_BR_002899



T69 Chain of Custody (2-08)

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), (b) Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property
Owner (b) (6), (b) (7)
Other

3. Location where property was acquired
(b) (6), (b) (7)(C) (b) (6), (b) (7)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.

OR130018BR-358 1 envelope 43 seeds of 03674/11 Express Romo vrl5 Het 2ns BC6 F3 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by	Date	Received By	Date
OR130018BR-358 (b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	11/16/13	(b) (6), (b) (7)(C)	11-16-13

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Control number or name

Page 1



OR120018_BR 002900

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), [redacted] Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property

Owner [redacted]
Other [redacted]

3. Location where property was acquired

(b) (6), (b) (7) (b) (b) (b) (b)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.

OR120018BR-359 1 envelope 6 seeds of 00683/5 x Express BC4 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by	Date	Received By	Date
OR120018BR-359 (b) (6), (b) (7)(C)	[redacted] Investigator	11/16/13	Deven R. See (b) (6), (b) (7)(C)	11-18-13

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

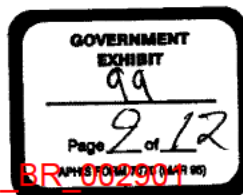
Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Control number or name _____

Page 1



OR120018 BR-002901

T69 Chain of Custody (2-08)

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), (b) Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property

Owner (b) [redacted]
Other [redacted]

3. Location where property was acquired

[redacted] (b) (6), (b) (7)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.

OR1200189R-360 1 envelope 10 seeds of 00675/1 x Express BC3 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR1200189R-360 (b) (6), (b) (7)(C)	[redacted] Investigator	11/16/13	Deven R. See (b) (6), (b) (7)(C)	11-16-13

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Control number or name _____

Page 1



OR1200189R-360

T69 Chain of Custody (2-08)

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), Investigator

Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property
Owner _____
Other _____

3. Location where property was acquired
(b) (6), (b) (7)(C), (b) (7)(C)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.
OR120018BR-361 1 envelope 11 seeds of 99659/5 x Express BC2 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR120018BR-361	(b) (6), (b) (7)(C) Investigator	11/16/13	Daven R. See (b) (6), (b) (7)(C)	11-16-13

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
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Control number or name _____

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OR120018 BR 002993



T69 Chain of Custody (2-08)

United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title
(b) (6), (b) (7)(C) Investigator
Receiver's Office and Location
Helena, MT

2. Full Name and Address of Person furnishing property
Owner (b) (6), (b) (7)(C)
Other _____

3. Location where property was acquired
(b) (6), (b) (7)(C)

4. Date of acquisition: 11/13/13

5. Purpose for which obtained: Research

6. Item Description of Articles
No. Quantity Include specimen no., serial no., seal no., identifying marks, and condition when appropriate.
OR130018BR-362 1 envelope 9 seeds of Express x 98629/2 BC1 wheat

7. Initiating official should appear as first person relinquishing item.

Item No.	Relinquished by	Date	Received By	Date
OR130018BR-362	(b) (6), (b) (7)(C)	11/16/13	(b) (6), (b) (7)(C)	11-16-13

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Item No.	Relinquished by	Date	Received By	Date
	Sign and Print Name		Sign and Print Name	

Control number or name _____

Page 1

T69 Chain of Custody (2-08)

OR120018 BR 002905



**United States Department of Agriculture Animal Plant Health Inspection Service
Chain of Custody**

INVESTIGATIVE AND ENFORCEMENT SERVICES

1. Receiving Official and Title

Alec Ormsby, SITC Officer
USDA APHIS PPQ

Receiver's Office and Location

Airport Business Center
6135 NE 80th Ave, Suite A-5
Portland, OR 97218

2. Full Name and Address of Person furnishing property

Owner: (b) (6),
(b) (6), (b) (7)
(C), (b) (4), OR (b)

3. Location where property was acquired

(b) (6), (b) (7)(C), (b) (4)

OR

4. Date of acquisition: Thursday, June 20, 2013

5. Purpose for which obtained: Analytical purposes

6. Subsequent handling:

On June 20, 2013, Alec Ormsby (APHIS PPQ) collected Item Nos. OR130018-BR-180 through OR130018-BR-327 from the field described above. On June 20, 2013, Office Ormsby relinquished Item Nos. OR130018-BR-180 through OR130018-BR-327 to (b) IES Investigator who hand delivered these samples and subsequently relinquished Item Nos. OR130018-BR-180 through OR130018-BR-327 to Dr. Deven R. See, Western Regional Small Grains Genotyping Center USDA-ARS, 209 Johnson Hall, Washington State University, Pullman, WA 99164. Dr. Deven R. See, who confirmed receipt by signing the Chain-of-Custody for the samples that (b)(6), (b) hand delivered (copy attached).

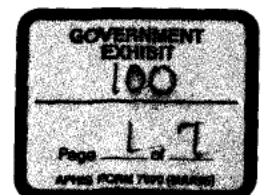
On July 22, 2013, Dr. Deven R. See prepared partial samples of Item Nos. OR130018-BR-180 through OR130018-BR-327 as described below and relinquished them to Tandace A. Bell, PhD, Chief, Biotechnology and Analytical Services Branch, USDA-GIPSA Technology and Science Division, 10383 North Ambassador Drive Kansas City, MO 64153.

On September 24, 2013, Dr. See prepared DNA samples of Item Nos. OR130018-BR-180 through OR130018-BR-327 as described below and relinquished them to Shiaoan Chao, Research Molecular Geneticist, USDA-ARS Biosciences Research Lab, 1605 Albrecht Blvd N, Fargo, ND 58102-2765.

7. Item**Description of Articles**

No.	Quantity	Include specimen no., serial no., seal no., identifying marks, and condition when appropriate
OR130018-BR-180-1	1	96 well A01
OR130018-BR-181-2	1	96 well A02
OR130018-BR-182 (2)-4	1	96 well A03
OR130018-BR-183-1	1	96 well A04
OR130018-BR-184-2	1	96 well A05
OR130018-BR-185-2	1	96 well A06
OR130018-BR-186-1	1	96 well A07
OR130018-BR-187-1	1	96 well A08
OR130018-BR-187-2	1	96 well A09
OR130018-BR-188-1	1	96 well A10
OR130018-BR-189-2	1	96 well A11
OR130018-BR-190-1	1	96 well A12
OR130018-BR-191-3	1	96 well B01
OR130018-BR-192-2	1	96 well B02
OR130018-BR-193-3	1	96 well B03
OR130018-BR-194-1	1	96 well B04
OR130018-BR-195-1	1	96 well B05
OR130018-BR-196-2	1	96 well B06

OR120018_BR_002907



OR130018-BR-197-1	1	96 well B07
OR130018-BR-198-1R	1	96 well B08
OR130018-BR-198-2W	1	96 well B09
OR130018-BR-199 (1)-2	1	96 well B10
OR130018-BR-199 (2)-3	1	96 well B11
OR130018-BR-200-3	1	96 well B12
OR130018-BR-200-4	1	96 well C01
OR130018-BR-201-2	1	96 well C02
OR130018-BR-202-1	1	96 well C03
OR130018-BR-203-1	1	96 well C04
OR130018-BR-203-2	1	96 well C05
OR130018-BR-204-1	1	96 well C06
OR130018-BR-204-2	1	96 well C07
OR130018-BR-205-1	1	96 well C08
OR130018-BR-206-1	1	96 well C09
OR130018-BR-207-2	1	96 well C10
OR130018-BR-208-3	1	96 well C11
OR130018-BR-209-2	1	96 well C12
OR130018-BR-210-1	1	96 well D01
OR130018-BR-211-1	1	96 well D02
OR130018-BR-212-1	1	96 well D03
OR130018-BR-213-1	1	96 well D04
OR130018-BR-214-2	1	96 well D05
OR130018-BR-215-1	1	96 well D06
OR130018-BR-216-2	1	96 well D07
OR130018-BR-217-1	1	96 well D08
OR130018-BR-218-2	1	96 well D09
OR130018-BR-219-1	1	96 well D10
OR130018-BR-220-1	1	96 well D11
OR130018-BR-221-1	1	96 well D12
OR130018-BR-222-1	1	96 well E01
OR130018-BR-223-1	1	96 well E02
OR130018-BR-224-1	1	96 well E03
OR130018-BR-225-2	1	96 well E04
OR130018-BR-225-3	1	96 well E05
OR130018-BR-226-2	1	96 well E06
OR130018-BR-227-2	1	96 well E07
OR130018-BR-227-3	1	96 well E08

8. Initiating official should appear as first person relinquishing item.

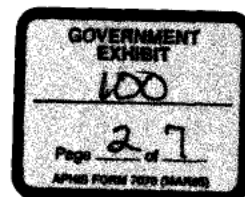
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-180-1	Dr. Deven See (b) (6), (b) (7)(C), (b) (4)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-181-2	Dr. Deven See (b) (6), (b) (7)(C), (b) (4)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13

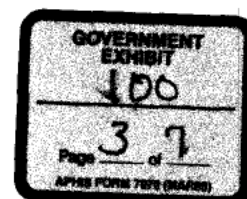
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-182(2)-4	Dr. Deven See (b) (6), (b) (7)(C), (b) (4)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13

Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-183-1	Dr. Deven See (b) (6), (b) (7)(C), (b) (4)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13

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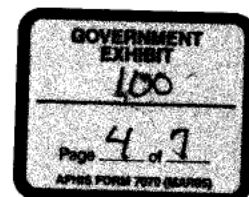


Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-184-2	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-185-2	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-186-1	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-187-1	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-187-2	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-188-1	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-189-2	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-190-1	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-191-3	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-192-2	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-193-3	Dr. Deven See (b) (6), (b) (7)(C)	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13



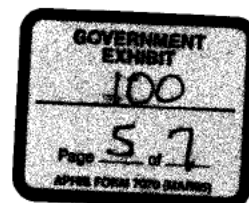
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-194-1 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-195-1 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-196-2 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-197-1 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-198-1R (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-198-2W (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-199(1)-2 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-199(2)-3 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-200-3 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-200-4 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-201-2 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-202-1 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13

OR120018_BR_002913



Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-203-1 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-203-2 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-204-1 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-204-2 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-205-1 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-206-1 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-207-2 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-208-3 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-209-2 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-210-1 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-211-1 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
OR130018-BR-212-1 (b) (6), (b) (7)(C)	Dr. Deven See	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13

OR120018_BR_002915



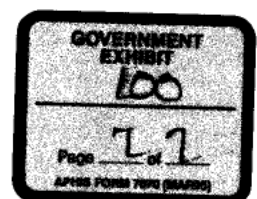
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-213-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-214-2	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-215-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-216-2	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-217-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-218-2	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-219-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-220-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-221-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
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Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-222-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
(b) (6), (b) (7)(C)		9-24-13		
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-223-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
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OR130018-BR-224-1	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
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OR130018-BR-225-2	Dr. Deven See	09/24/13	Dr. Shiaoman Chao	09/25/13
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OR130018-BR-225-3 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-226-2 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
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OR130018-BR-227-2 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13
Item No.	Relinquished by Sign and Print Name	Date	Received By Sign and Print Name	Date
OR130018-BR-227-3 (b) (6), (b) (7)(C)	Dr. Deven See [REDACTED]	09/24/13 9-24-13	Dr. Shiaoman Chao	09/25/13

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Molecular marker analysis for Mon71800 germplasm identification

The following is an interpretive summary of molecular marker work on wheat samples that putatively contained the transgenic trait Mon71800 conferring glyphosate resistance. This work was performed by the USDA-ARS at the Western Regional Small Grains Laboratory Pullman, WA. The 90K SNP marker panel was generated by the USDA-ARS Biosciences Research Lab 1605 Albrecht Blvd N, Fargo, ND 58102-2765.

In the middle of May 2013, the Western Regional Small Grains Laboratory was contacted by APHIS to discuss the possibility of performing molecular marker analysis on unknown wheat material which putatively contained the Mon71800 gene for Glyphosate resistance. The purpose of the molecular marker analysis was to determine if the unknown wheat material could be genetically linked to known wheat cultivars which would help determine from where the material arrived.

DNA samples utilized in this project were derived from multiple sources. Sample material arrived June 5th 2013 in the form of DNA from USDA, Agriculture Marketing Service. Due to the limited amount of DNA in these stocks (see excel file, tab, Timeline 6-6-2013), few markers were able to be analyzed. Initial testing included 50 unknown samples from APHIS and 28 known wheat cultivars (see excel file, tab, APHIS AMS SSR) selected because they were grown in the same region as the unknown wheat was found. In late June additional DNA of the original 50 samples was requested from APHIS, samples came from GIPSA and AMS. Multiple markers were repeated on this material to validate that it was in agreement with the original DNA. Other material arrived during this time in the form of 48 transplanted samples (BR 180 – BR 227) and 100 bags of leaf material (BR 228- BR 327) from the field in question. These live plants were placed in a locked growth facility and allowed to mature. Once mature, single seeds from each spike were selected and grown out for DNA.

A couple of notes on the last batch of material that arrived from the field; first in observing the transplanted material it was noted that while the majority of the plants had awns on the spikes (see excel file, tab, BR DNA SSR), some of the plants were awnless. Also in at least one pot, BR 198, there were some spikes with awns and some spikes without awns. These observations indicated that there was morphological diversity in the material collected and that some pots contained more than one plant. This subset of material, while having diversity both within samples and among samples, offered the best solution for DNA testing, as we only used single seeds from each spike as an individual sample, we could generate large quantities from tissue grown in controlled conditions.

Multiple marker technologies were used in the analysis of the unknown material. Initially Single Nucleotide Polymorphism (SNP) markers were run on these stocks. SNP markers are more





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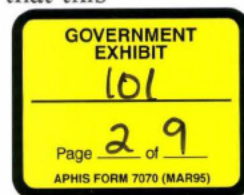
responsive to high throughput technologies, and require less DNA per analysis, as such are a logical choice for rapid analysis of unknown samples. Results from the initial testing against the 50 samples suggested the plants were highly variable. Simple Sequence Repeats SSR markers were chosen for further analysis. One downside to SNP markers is that they are less polymorphic than SSR markers. SSR markers are hypervariable (highly polymorphic), and as such are an excellent choice for genotyping. However, SSR markers require more DNA per reaction than SNP markers, and are labor intensive to generate and score marker profiles.

A technical note on how to read SSR marker results; in the excel file containing results from the marker analysis for SSR's, the number is a representation of the PCR amplicon size (number of nucleotides amplified) from an individual sample, example, in the excel file APHIS AMS SSR, for the marker WMC720, sample 1C had an allele of 134bp, (bp = base pairs) while sample 33C had an allele of 149bp, this indicates that there are 15 additional nucleotides at this molecular marker in 33C than in 1C.

APHIS, GIPSA, AMS, DNA SSR Analysis

Initial analysis of the 50 samples and 28 known cultivars with SSR markers indicated that the unknown samples with the Mon71800 event did not exactly match any of the known cultivars compared against them. In the first tests 15 SSR and 3 sequence tagged site (STS) markers indicated that the unknown samples were most closely related to two cultivars Expresso and Solano (see excel file, tab, APHIS AMS SSR summary, column AJ "% identity"). Solano had the highest similarity with 83.3% identity with the most frequent alleles present in the unknown samples, Expresso was 77.7% identical. The other known cultivars used in these assays ranged in similarity from 11.1% for Geotze to 61.1% identity with Nick. Additional STS markers were also analyzed to see if a specific market class could be associated with the unknown samples. The markers for seed hardness PinA and PinB were run; a definitive result could not be derived from these assays, as some samples were missing the PinA 354bp allele (APHIS AMS SSR column BQ), absence of this allele usually indicates a hard variety. Seed coat color was examined using newly developed KASP markers (a variant of SNP marker technology). While the majority of the unknown samples indicated that the seeds were white, some of the unknown samples had the presence of the allele that was indicative of the red gene being present in one of the three wheat genomes (APHIS AMS SSR column BM); note lower case aa,bb,dd indicates that the sample has the white allele at all three genomes, upper case (example 27C) aa,BB,dd indicates that the sample has one red allele in the B genome, and as such will have red seed coat color. The vernalization markers were also ran, however, no clear information could be gathered from these markers.

The preliminary conclusions that were derived from the initial marker analysis on the DNA of the unknown samples indicated that the unknown samples as a whole were heterogeneous (not the same as each other). The heterogeneous nature of the material is a strong indication that this





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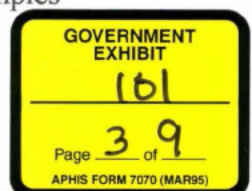
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material is germplasm from a breeding program and not a released cultivar. Cultivars are normally highly homogeneous both in phenotype and genotype, and show very low levels of heterogeneity at the DNA level. The unknown samples showed only a low level of heterozygosity indicating that the material was not of an early generation in a cross. The unknown samples had a high similarity to two released cultivars, Espresso and Solano, indicating that the unknown material shared a genetic makeup that is present in both of these cultivars, the cultivar Express is the key cultivar that was used in the development of both Espresso and Solano and information obtained from APHIS lists Express as one of the cultivars used for introgressing the Mon71800 event. Based on this information it was concluded that providing an identical match to a known cultivar was not possible due to the heterogeneous nature of the unknown material, as such the focus of further research shifted to identifying the genetic makeup of the unknown material, comparing the unknown samples against a larger panel of known cultivars, analyzing the genetics of the cultivars that were used in the development of Espresso and Solano and testing larger samples of key cultivars like Express, Espresso, and Solano. The larger sample size testing for Espresso and Solano was decided because both cultivars have variants listed in their registration for white off-types (see attached PDF files for registration information), Espresso also has a variant listing for awnless, as observed in some of the 48 transplanted samples.

APHIS Field Sample SSR Analysis

Seeds collected from each spike of the 48 transplanted samples were germinated, tissue was collected and DNA extracted. After harvesting leaf material, the plants were kept in the growth chamber to observe the growth habits of the material to help access spring, winter growth habit (excel file, tab, BR DNA SSR, column E). As can be seen in the growth habit of the material the samples had early spring, spring, late spring and winter growth habits and in some cases growth habit segregated within samples. While multiple components contribute to winter vs. spring growth habit, including the vernalization genes, and photoperiod, it is hard to determine between late spring and winter growth habit if the plant requires vernalization or is late heading. A strong winter growth habit requires 8 weeks of vernalization (exposure to $< 10^{\circ}\text{C}$) to allow the plant to transition from vegetative to reproductive phase of growth; at this point the winter samples are still undergoing vernalization.

A few of the transplanted samples were late in spike maturity and were not harvested at the same time, these samples were included in analysis at a later date, however, the tissue from the initial harvesting of spikes generated 156 samples which provided a reasonable sized dataset to analyze. Each potted plant produced multiple spikes, as each single seed from a spike was treated as a separate sample, this provided the ability to identify if multiple plants were within each pot, and also provided quality control in the case that multiple samples were derived from the same plant (see excel file, tab BR DNA SSR, column D). Other material developed for this testing phase included 191 samples from all market classes comprised primarily from released cultivars, multiple samples from white off-type variants from Espresso and Solano, and multiple samples





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from Express. Other released cultivars derived from Express including Plata, Patwin, WB Rockland, WB Cristallo, and Blanca Grande were also assayed.

For the genetic analysis of the 156 BR samples an additional 30 SSR markers were assayed, many of these markers were also run on the market class DNA samples (see excel file, tab, MC SSR), multiple Espresso red, Espresso white and Express samples (see excel file, tab, BR DNA summary columns I & J). In looking at the results from the SSR work on the 156 samples (BR DNA SSR), multiple alleles were present among the samples as was also seen in testing the DNA from APHIS. The alleles are color coded to indicate allele frequency within the 156 samples (green most common, blue second, yellow third). A few markers like wmc128 had only one allele present in all samples, however, most makers showed at least two different alleles. Because each sample was derived from a single seed, and most of the transplanted samples produced multiple spikes, we were able to determine that in a few of the pots specifically BR samples 187, 194, 199, 203 and 227, multiple plants were represented. The Mon71800 marker was run multiple times on the 156 samples, first with conventional DNA polymerase (NEB TAQ) and also with the DNA polymerase stated in the official protocol (Red TAQ) see Tab BR DNA SSR columns X & Z, samples 180-1,2, 184-1,2, and 198-1,2,3 consistently did not amplify the Mon71800 allele, all other samples showed the presence of the Mon71800 allele. Additional STS markers run on this panel including the KASP markers for seed coat color (column CU), the Ventriup marker which detects the presence of the Yr17 stripe rust resistance gene derived from the alien introgression from *Triticum ventricosum* that is present in the wheat cultivar Madsen. This marker is difficult at times to get good reproducible results; however, after multiple runs of this marker it was concluded that samples 217-1 and 217-2, two samples from the same plant had the positive allele for the Yr17 gene. The grain hardness markers were also ran, both the PinB and PinA and PinA null. These markers indicated that both hard and soft wheat seed was present in the material.

The 'BR DNA summary' tab summarizes the results from the SSR analysis; it also included results from the analysis of multiple Express and Espresso red and white variants (white seeds were hand selected from a large quantity of Express and Espresso seed) which increase the detection threshold of rare alleles. The conclusion of the SSR work indicated that Express red and white variants shared alleles with the 156 samples at a frequency of 93.3%, Espresso red and white variants had a frequency of 86.6% and Solano, which was too uniform to isolate white variants, was at 76.7%. These frequencies were derived from presence of all alleles in the 156 samples as well as alleles identified not only in Express and Espresso, but also the off-type white variants in these varieties. Now with a more precise understanding of what the SSR markers were indicating, SNP markers could be reinvestigated as a tool to see if more information could be extracted from the unknown material.





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APHIS Field Sample SNP Analysis

The final molecular marker analysis that was assayed on this material was done utilizing newly discovered SNP markers in wheat. Fifty six of the unknown samples representing all of the 48 original transplanted plants and a few additional where multiple plants may have been present were selected. Thirty nine known cultivars were also included and in the case of Express, Espresso and Espresso white (GIPSA W E07, GIPSA W A07, GIPSA W C08), multiple samples were included. While SSR markers are more informative, SNP markers can be run in a high throughput capacity; in this case ~81,500 SNP markers were assayed against the 95 samples. Out of the ~81000, 5442 have a known genetic position in the wheat genome based upon comparative mapping efforts. These 5442 SNP markers were selected to evaluate the genetic structure of the genome on the unknown samples and used to make comparisons against the known cultivars. Initial analysis of the SNP markers indicated that multiple samples clustered into groups. Group 1: is represented by BR samples 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216; group 2: 180, 181, 182, 183, 184, 185, 186, 187, 188, 190; group 3: 218, 219, 220, 221, 222, 223, 224, 225, 226. This grouping is related to the sampling location within the field and indicates that genetically related samples were clustered in the field. Group 1 is related at the 99.5% range indicating all the samples in this group are essentially genetically. Group 2 is related at the 92% to 99% range, group 3 is related at the 99% range (excel file, tab, SNP distance matrix). Group 1 is related to group 2 by 90%, group 1 to group 3 by 90% and group 3 is related to group 2 by 95%. The other BR samples 187-1, 187-2, 189, 191, 192, 193, 194, 195, 196, 197, 198-1R, 198-2W, 199 (1)-2, 199 (2)-3, 200-3, 200-4, 201, 203-1, 203-2, 217-1, 227-2, and 227-3 while clustered together in the molecular phylogeny do not form a tight genetic group and are related to the three groups between 80% and 86%. These grouping can be seen in the molecular phylogeny of the 95 individuals, sample name coding can be found in the attached PDF file 'genome phylogeny.' Page 22 is the whole genome representation of the molecular relatedness of the 56 BR samples against the known cultivars. Sample seq64 which is the Espresso white variant sample GIPSA W E07 was the most closely related known cultivar at 82.6% similarity to the samples. To determine what other genetic material may be present in the unknown samples the SNP markers were ordered by chromosome (excel file, tab, BR DNA SNP, column B) and genetic position on chromosome (excel file, tab, BR DNA SNP, column C), then screened against putative cultivars that could be present like Bobwhite, Madsen and Avocet Yr15.

Some background information is needed to explain why Bobwhite, Madsen and Avocet Yr15, may be present within the genomes of the unknown BR samples; Bobwhite has a long history of being the only wheat cultivar that can be transformed efficiently, as such scientists working with wheat utilize this cultivar when inserting foreign DNA into wheat, the now transformed Bobwhite can be crossed with any other wheat to move the foreign DNA into regionally adapted cultivars. Transformed means the insertion of a genetically modified trait into the wheat genome, the usual way this occurs is through





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biolistic bombardment of naked DNA into wheat cells, then regeneration of the transformed plant. It was known that Express was being used as a host for the Mon71800 event, however, Express is susceptible to the current races of the stripe rust fungus; during this same time period, Expresso was being developed by crossing Yr15 and Yr17 from Avocet and Madsen, respectively, into Express (see PDF Expresso). In this way, Yr15 and Yr17 were introgressed into Express to create Expresso, a stripe rust resistant cultivar.

To analyze segments of the wheat genome that are consistent with specific cultivars, linkage blocks (clusters of markers linked together genetically) are assayed to identify similarity with the cultivars in question. Graphical representation of this test can be seen in the attached files labeled (All vs 182, All vs 207, All vs 219 and Express vs Gip 207 182 219). In these files All is represented by Avocet Yr15, Bobwhite, Gipsa W E07, and Madsen; 207 182 and 219 are representatives of group 1, 2 and 3, respectively. In looking for segments of chromosomes in detail (excel file, tab, BR DNA SNP) derived from Bobwhite (column L) an example can be seen between rows 542 – 577, this cluster of 37 SNP markers are identical between Bobwhite and all BR samples. Another example can be seen between rows 4415 – 4490; in this case Bobwhite is identical to BR groups 1 and 2. For Avocet Yr15 an example can be observed between rows 2254 – 2321 where groups 1 and 2 are identical while group 3 is identical to Express. An example of Madsen can be seen between rows 4511 – 4593, this group of 83 SNP markers is identical to groups 1 and 2 while group 3 is identical to Express. Multiple segments can be seen with identity to Express, one example can be seen between rows 3236 – 3338, this segment is identical to BR group 1. For the white off-type Expresso (Gipsa W E07) which was genetically the closest match to the BR samples, one example can be seen between rows 953 – 1128, this block with 176 SNP markers is identical to group 1.

Conclusions:

Multiple samples were tested in attempting to identify the source of the glyphosate resistant transgene. While multiple laboratories tested and validated that the unknown material contained the Mon71800 event, the identification of a cultivar with an exact match to the unknown material could not be identified. This laboratory has done many projects where an unknown must be matched to putative cultivars, in all cases a small number of SSR or SNP markers are usually needed to develop a perfect match to a cultivar. The main reason why the unknown material in this study did not find an exact match to the more than 200 cultivars it was compared against is due to the fact that the unknown material is not a released cultivar. A released cultivar is very homogeneous genetically, typically 99.7% identical between individuals (see excel file, tab, SNP Distance matrix, samples: Express D01, Express D02, Express D03, Express D05,). The unknown material, genetically, looks like germplasm from a breeding program that was still in the selection process. Multiple facts point to this conclusion; first phenotypically the unknown material contained both winter and spring growth habits, molecular





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markers for grain hardness indicated both hard and soft kernels, and markers for seed coat color indicated both white and red seeds. Genetically the SSR and SNP marker work on the samples derived from the transplanted material indicated that within groups 1, 2, and 3, samples were genetically very similar. However, between groups the samples showed genetic diversity. Once it was concluded that an exact match could not be found, trying to understand what cultivars contributed to the unknown material became the focus. While other cultivars showed similarity to the unknown material (including varieties that did not have Express in their pedigrees, like Malcom and Foote), based on the molecular marker work performed that involved Solano, Express, Espresso and their white off-type variants, other than Express, Espresso had the highest genetic similarity to the unknown material. As mentioned earlier, Espresso, a hard red spring (HRS), was bred by a two-way backcross with Avocet, a HRS, and Madsen, a soft white winter (SWW), to introduce stripe rust resistance, at the same time that Mon71800 was bred into Express. The SNP analysis shows strong evidence that both Madsen and Avocet are present in the unknown material. The phenotypic data also indicates that both white and red wheat were involved in the cross as well as a winter and spring wheat, both of these criteria are met with a cross where Madsen was involved with Express. A specific molecular test for the alien translocation from Madsen proved one sample, duplicated, had this gene present, why all samples did not have this gene cannot be answered, however, the fact that one sample contained the gene indicates that this material must have been crossed with material containing the *Triticum ventricosum* segment.

In the time frame that this research was done, all of our tests, primarily the result of the SSR work, but supplemented with the SNP analysis, concluded that the genetic characteristics of the wheat volunteers are representative of an early stage of a wheat breeding program, not a released wheat cultivar, and as such, further testing is unlikely to result in identifying an identical match to a known cultivar.

Table and Figure legends:

Table 1: Excel file Final Report;

Tab, APHIS AMS SSR; column B is the position within wells for tracking samples. Sample name is the designations given to the samples from APHIS; marker names like WMC, BARC, and GWM are the names of the DNA primers used to amplify a specific allele from wheat. The number below marker names is the size in DNA base pairs of the amplified allele. Any missing wells denote a PCR reaction where either the quality of amplified fragment was poor or the sample did not work. Wells with 96 well or 384 well in the title are plate coordinates and were left in for sample tracking purposes.

Tab, APHIS AMS SSR summary; marker alleles are color coded to denote frequency among samples, (green most frequent, Blue second). APHIS samples in red had the MON71800 event, blue were samples also collected. The percent identity of known cultivars to the unknown samples is in column AJ.





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Tab, BR DNA SSR; the 48 transplanted pots from the field provided the BR samples. As individual seeds from each spike were used to generate the DNA for these tests, most all of the 48 samples are represented more than once and indicated by the -1 -2 -3 in the sample names in column D. growth habit is in column E, spike morphology is in column F. Marker alleles are color coded to denote frequency among samples, (green most frequent, Blue second, yellow third). AMS samples were used in rows 158-161 as some DNA was still available from these samples. BR325, BR326 and BR327 was derived leaf material from the field collection.

Tab, BR DNA summary; summarizes the results from the raw analysis, frequency of alleles is denoted with color for the BR DNA, alleles present in the AMS and BR field collected tissue is also present. The Express, Espresso Solano and Blanca Grande alleles are highlighted if they were the same as the most frequent allele in the BR DNA. Espresso R V W denoted the alleles that were present when the multiple Espresso white and red samples were tested. In column J multiple Express samples were tested and the alleles present are indicated. Row 35 indicated the percent identity the known cultivars had in common with the BR DNA samples for the most frequent allele. Row 36 is the percent identity the known cultivars had with all alleles present in the BR DNA samples.

Tab, MC SSR; the Market Class samples comprised mostly from released cultivars and SSR markers results are denoted. SSR alleles are color coded as described earlier. Percent identity of the two most common alleles to the unknown samples is shown in column AF.

Tab, BR DNA SNP; the 5442 SNP markers that were analyzed on the BR DNA and known cultivars are shown here. Columns A list the SNP name, column B is the wheat chromosome name, column C is the genetic position on the wheat chromosome in (centiMorgan units (cM). Row 1 indicates the known grouping of the BR DNA, row 2, from column E onward is the sample name. SNP calls are given in nucleotide composition.

Tab, SNP Distance matrix; the sample names are in both column A and row 1 the identifier used in the molecular phylogeny is given in row 2 and column B. the distance matrix is used to generate the molecular phylogeny and list the genetic difference approximation between any given sample included in the test.

PDF documentation:

Molecular phylogeny; this PDF document contains the molecular phylogenies of all 95 samples tested with 5442 SNP markers for each of the 21 chromosomes of wheat as well as the whole genome level. The sample coding key can be found at the end of the document as well as in the excel file with the distance matrix that was used for the whole genome phylogeny. The order of samples in the molecular phylogeny is the same as in the excel file, tab, SNP Distance Matrix. The last two pages on the PDF document with seq numbers does not correctly reflect the seq number used in the molecular phylogenies.

The two additional PDF documents contain registration information for Espresso and Solano





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TIFF images:

Three of the TIFF images represent a whole genome visualization of the SNP linkage blocks color coded to compare Avocet Yr15 blue, Bobwhite red, Gipsa W E07 green (Expresso white variant), and Madsen brown, against BR samples 207 182 and 219 which are representatives of group 1, 2 and 3, respectively. The TIFF image Express vs. Gipsa W E07, 207, 182, 219 is a comparison of the three groups and the white Expresso variant against Express.



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File Number: 3174788 **Incorporation Date /** 02/09/2000
(mm/dd/yyyy)
Formation Date:

Entity Name: MONSANTO COMPANY

Entity Kind: CORPORATION **Entity Type:** GENERAL

Residency: DOMESTIC **State:** DE

REGISTERED AGENT INFORMATION

Name: CORPORATION SERVICE COMPANY

Address: 2711 CENTERVILLE RD STE 400

City: WILMINGTON **County:** NEW CASTLE

State: DE **Postal Code:** 19808

Phone: (302)636-5401

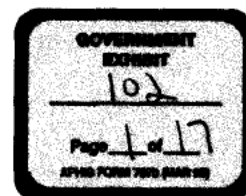
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Business Information Report

Purchase Date: 07/08/2013
Last Update Date: 04/17/2013
Attention: usda

Executive Summary

Company Info

Year Started 2000
Control Year 2000
CEO HUGH GRANT, CHB-CEO
Employees 21,500
Employees Here 3,000 at this location
Working Capital \$7,327,000,000

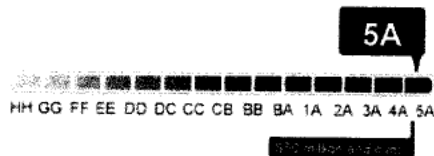
Trade Styles MONSANTO
Sales (Financial Statement) \$13,504,000,000
Net Worth (Financial Statement) 14,078,000,000
As of 05/31/2013

D&B Rating

D&B Rating

5A2

Financial Strength

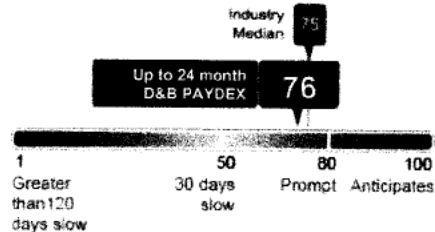


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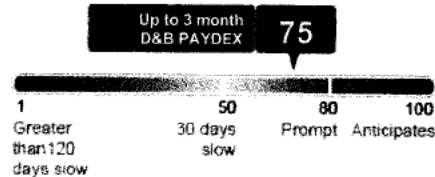


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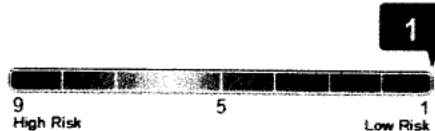
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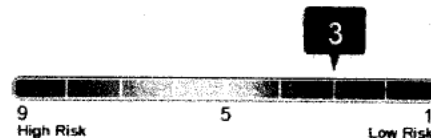
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Data Depth Indicator

Portfolio Comparison



Company Profile



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Financial
Data

Available

Trade
Payments

Available
(3+Trade)

Company
Size

Large

Years in
Business

Established

Business Information

Business Summary

Branch & Division YES
Financing SECURED
Financial Condition STRONG
SIC 2879
Mfg agricultural
chemicals & seeds
NAICS 325320
Pesticide and
Other Agricultural
Chemical
Manufacturing
History Status CLEAR

Credit Capacity Summary

D&B Rating

5A2

Financial Strength

HH GG FF EE DD CC CB BB BA 1A 2A 3A 4A 5A

Composite Credit Appraisal

4 Limited 3 Fair 2 Good 1 High

Prior D&B Rating 5A2
Rating Date 08/22/2005

Payment Activity (based on 794 experiences) USD

Average High Credit \$205,058
Highest Credit 30,000,000
Total Highest Credit 142,829,250

D&B Viability Rating

The D&B Viability Rating uses D&B's proprietary analytics to compare the most predictive business risk indicators and deliver a highly reliable assessment of the probability that a company will no longer be in business within the next 12 months.

Viability Score

9 High Risk 5 1 Low Risk

Compared to All US Businesses within D&B Database:

- Level of risk: **Low Risk**
- Businesses ranked 1 have a probability of becoming no longer viable: **0.2%**
- Percentage of businesses ranked 1: **0.3%**
- Across all US businesses, the average probability of becoming no longer viable: **14%**

Portfolio Comparison

9 High Risk 5 1 Low Risk

Compared to all Businesses within the same MODEL SEGMENT:

Model Segment: Available Financial Data



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- Level of risk: **Low Risk**
- Businesses ranked 3 within this model segment have a probability of becoming no longer viable: **0.2%**
- Percentage of businesses ranked 3 within this model segment: **15%**
- Within this model segment, the average probability of becoming no longer viable: **0.6%**

Data Depth Indicator



Data Depth Indicator Details:

- ✓ Rich Firmographics
- ✓ Extensive Commercial Trading Activity
- ✓ Comprehensive Financial Attributes

Company Profile

Financial Data	Trade Payments	Company Size	Years in Business
Available	Available (3+Trade)	Large	Established

Company Profile Details:

- Financial Data: **Available**
- Trade Payments: **Available (3+Trade)**
- Business Size: **Large** (Employees: 50+ or Sales: \$500K+)
- Years in Business: **Established (5+)**

Business History

Officers
HUGH GRANT, CHB-CEO+;
BRETT BEGEMANN, PRES-CHIEF COMML OFFICER;
PIERRE C COURDURoux, SR V PRES-CFO;
ROBERT T FRALEY, EXEC V PRES-CTO;
DAVID F SNIVELY, EXEC V PRES-SEC-GEN CNSL

Directors
David L Chicoine PhD, Janice L Fields, Arthur H Harper, Laura K Ipsen, Gwendolyn S King, C Steven Mcmillan, Jon R Moeller, William U Parfet, George H Poste PhD, Robert J Stevens and Gregory H. Boyce.

As of 04/17/2013

Incorporated in the State of Delaware on February 9, 2000.

Business started 2000.

On Dec 19, 1999, old Monsanto and Pharmacia & Upjohn, Inc announced a plan to create a wholly owned subsidiary, named Monsanto Company, and to offer up to 19.9% of Monsanto Company in an initial public offering. Upon completion of the public offering, Pharmacia was to own at least 80.1% of outstanding common stock. Monsanto Company was incorporated in February 2000 under Delaware law as a subsidiary of Pharmacia Corporation, and is comprised of the operations, assets and liabilities that were previously the agricultural division of Pharmacia. On September 1, 2000, the assets and liabilities of the agricultural business were transferred from Pharmacia to Monsanto, pursuant to the terms of a Separation Agreement dated as of that date. At the close of business on Aug 13 2002, Pharmacia Corp distributed to its shareholders all the common stock owned at a rate of 0.170593 shares of Monsanto for each share of Pharmacia. Following the transaction, Pharmacia retained no interest in the business.

The company's common stock is traded on the New York Stock Exchange under the symbol "MON". As of October 15, 2012, there were 36,134 shareholders of record. As of November 1, 2012, there was no one shareholder identified by the company as beneficially owning 5% or more of the outstanding shares. As of the same date, officers and directors as a group beneficially owned less than 1% of the outstanding shares.

RECENT EVENTS.

On February 7, 2013, sources stated that Monsanto Company, Saint Louis, MO, has acquired select assets of Agradis, Inc., on January 30, 2013. Monsanto's purchase includes the Agradis name and its collection of microbes that can improve crop productivity. Monsanto has also acquired the company's R&D site in La Jolla, California. Additional details were not disclosed.

On May 23, 2012, the company acquired Precision Planting Inc., Tremont, IL, for a total consideration of approximately \$255 million.



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On September 28, 2011, the company acquired Beeologics LLC, Miami, FL.

On February 22, 2011, the company acquired Divergence, Inc., Saint Louis, MO, for a total consideration of approximately \$71 million.

HUGH GRANT. Director since 2003. He has served as CHB and CEO of the company since August 2012 and previously served as CHB, President and CEO of the company from October 2003 to August 2012. He was the President and CEO from May 2003 to October 2003, and Executive Vice President and COO from 2000 to 2003. He was the Co-President, Agricultural Sector, Former Monsanto Company from 1998 to 2000.

BRETT BEGEMANN. He has served as President and Chief Commercial Officer of the company since August 2012. From June 2003 to October 2007, he served as Executive Vice President, International Commercial. He also served as Executive Vice President, Global Commercial from October 2007 to October 2009 and as Executive Vice President, Seeds and Traits from October 2009 to January 2011. From January 2011 to August 2012, he served as Executive Vice President and Chief Commercial Officer.

PIERRE C COURDURoux. He has served as Senior Vice President and CFO of the company since January 2011 and previously served as Finance Lead of EMEA of the company from September 2004 to October 2007. He was also the Global Finance Lead of Vegetables Business from October 2007 to December 2009 and Global Seeds & Traits Finance Lead from December 2009 to January 2011.

ROBERT T FRALEY. He has served as Executive Vice President and CTO of the company since August 2000.

DAVID F SNIVELY. He has served as Executive Vice President, Secretary and General Counsel of the company since September 2006 and previously served as Senior Vice President, Secretary and General Counsel from September 2008 to September 2010.

DAVID L CHICOINE PHD. Director since 2009. He is the President of South Dakota State University and Professor of Economics.

JANICE L FIELDS. Director since 2008. She is the President of McDonald's USA, LLC.

ARTHUR H HARPER. Director since 2006. He is a Managing Partner at GenNx360 Capital Partners.

LAURA K IPSEN. Director since 2010. She is the Corporate Vice President, Worldwide Public Sector of Microsoft Corp.

GWENDOLYN S KING. Director since 2001. She is the President of Podium Prose.

C STEVEN MCMILLAN. Director since 2000. Retired CHB and CEO of Sara Lee Corporation.

JON R MOELLER. Director since 2011. He is the CFO of The Procter & Gamble Company.

WILLIAM U PARFET. Director since 2000. He is the CHB, President and CEO of MPI Research, Inc.

GEORGE H POSTE PHD. Director since 2003. He is the CEO of Health Technology Networks.

ROBERT J STEVENS. Director since 2002. He is the CHB and CEO of Lockheed Martin Corporation.

GREGORY H. BOYCE. Prior to joining Peabody, Boyce served as chief executive officer energy for international mining company Rio Tinto, with responsibility for a worldwide coal and uranium portfolio. Other prior positions include president and chief executive officer of Kennecott Energy Company and president of Kennecott Minerals Company.

Government Activity Summary

Activity Summary		Possible candidate for socioeconomic program consideration	
Borrower	No	Labor Surplus Area	YES (2013)
Administrative Debt	Yes	Small Business	N/A
Grantee	Yes	Women Owned	N/A
Party Excluded from Federal Programs	No	Minority Owned	N/A
Public Company	Yes		
Contractor	No		
Importer/Exporter	N/A		

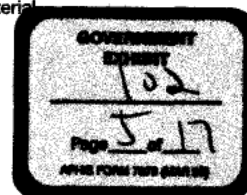
The details provided in the Government Activity section are as reported to Dun & Bradstreet by the federal government and other sources.

Operations Data

As of 04/17/2013

Description: The company together with its subsidiaries provides agricultural products for farmers. It operates in two segments, Seeds and Genomics and Agricultural Productivity.

The Seeds and Genomics segment produces corn, soybean, canola, and cotton seeds, as well as vegetable seeds, including tomato, pepper, melon, cucumber, pumpkin, squash, beans, broccoli, onions, and lettuce seeds. This segment also develops biotechnology traits that assist farmers in controlling insects and weeds, as well as provides genetic material and biotechnology traits to other seed companies.



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The Agricultural Productivity segment offers glyphosate-based herbicides for agricultural, industrial, ornamental, and turf applications; lawn-and-garden herbicides for residential lawn-and-garden applications; and other herbicides for the control of preemergent annual grass and small seeded broadleaf weeds in corn and other crops. The Company offers row crop seeds principally under the DEKALB, Asgrow, Deltapine, and Vistive brand names; vegetable seeds under the Seminis and De Ruiter brand names; traits primarily under the Roundup Ready, Bollgard, Bollgard II, YieldGard, YieldGard VT, Genuity, Roundup Ready 2 Yield, and SmartStax brand names; seed treatment products under the Acceleron brand name; and herbicide products under the Roundup and Harness brand names. It also licenses germplasm and trait technologies to seed companies.

Terms are on contract basis. Brands include DEKALB, Asgrow, Deltapine, Vistive, Seminis and De Ruiter Channel, SmartStax, YieldGard, YieldGard VT Triple, VT Triple PRO and VT Double PRO, Bollgard, Roundup Read and Genuity. Sells to retailers and commercial concerns. Territory : International.

Season peaks 2nd & 3rd quarter.

Employees: 21,500 which includes officer(s). 3,000 employed here. The company also employs more than 4,500 temporary employees.

Facilities: Owns premises in a building.

Special Events

As of 07/01/2013

MERGER/ACQUISITION: According to published reports, Monsanto Company, DUNS 168428287, (Saint Louis, MO) announced that it has acquired GrassRoots Biotechnology, Inc., DUNS 805889412, (Durham, NC). The terms of the Monsanto's acquisition of GrassRoots were not disclosed.

As of 06/10/2013

STOCK/BOND ISSUANCE/REDEMPTION/REPURCHASE: According to published reports, Monsanto Company announced that its Board of Directors has approved a new three-year share repurchase program. Monsanto's board authorized a new share repurchase program, effective July 1, 2013, for up to \$2 billion of the company's common stock over a three-year period. The new program will commence at the completion of Monsanto's existing \$1 billion share repurchase program, which was effective beginning in July 2012.

As of 04/17/2013

BOARD OF DIRECTORS UPDATE: According to published reports, Monsanto Company announced the appointment of Gregory H. Boyce to the company's board of directors.

As of 02/27/2013

PURCHASE OF ASSET: According to published reports, Monsanto Company, DUNS 168428287, (Saint Louis, MO) announced that it has acquired a portion of Synthetic Genomics, Inc., DUNS 623775660, (La Jolla, CA). Financial details were not disclosed.

As of 01/31/2013

PURCHASE OF ASSET: According to published reports, Monsanto Company, DUNS 168428287, (St. Louis, MO) announced it has purchased select assets of Agradis, Inc., DUNS 027151691, (La Jolla, CA). Monsanto's purchase includes the Agradis name and its collection of microbes that can improve crop productivity. Additional details were not disclosed.

As of 01/29/2013

ANNOUNCED SALE OF ASSET: As previously reported on September 13, 2012, Dongbu Hannong Co Ltd, South Korea announced that it is acquiring the seed business of Monsanto Co, Saint Louis, MO for an undisclosed value.

Industry Data

SIC

Code	Description
28790000	Agricultural chemicals, nec
01810303	Seeds, vegetable: growing of

NAICS

Code	Description
325320	Pesticide and Other Agricultural Chemical Manufacturing
111422	Floriculture Production

Family Tree

Divisions Domestic

MONSANTO COMPANY
(D-U-N-S®:14-023-8994)
AKA: MONSANTO
1512 NC HIGHWAY 55
W,
MOUNT OLIVE, NC
28365-7508

MONSANTO COMPANY
(D-U-N-S®:16-884-8653)
AKA: MONSANTO
304 CENTER ST,
WEST FARGO, ND
58078-1209

Branches Domestic

MONSANTO

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COMPANY
(D-U-N-S®:00-180-6962)
AKA: MONSANTO
2500 WIGGINS RD,
MUSCATINE, IA
52761-9138

COMPANY
(D-U-N-S®:00-259-1352)
AKA: MONSANTO
1081 A HARKIN RD,
TRACY, CA 95376

COMPANY
(D-U-N-S®:00-714-0700)
AKA: MONSANTO
MOKULELE HWY,
KIHEI, HI 96753

COMPANY
(D-U-N-S®:00-770-2405)
AKA: MONSANTO
310 MAIN ST NE,
MAPLETON, MN
56065

COMPANY
(D-U-N-S®:00-748-7932)
AKA: MONSANTO
825 WELLESLEY
PLACE DR,
CHESTERFIELD, MO
63017-0747

MONSANTO
COMPANY
(D-U-N-S®:00-862-4434)
AKA: MONSANTO
703 E BENTON ST,
OXFORD, IN 47971-8683

MONSANTO
COMPANY
(D-U-N-S®:01-024-8599)
AKA: MONSANTO
1010 BATEMAN ST,
PERRY, IA 50220-1466

MONSANTO
COMPANY
(D-U-N-S®:01-222-2480)
AKA: MONSANTO
17050 S 192ND ST,
GRETNA, NE 68028-6736

MONSANTO
COMPANY
(D-U-N-S®:01-299-2462)
AKA: MONSANTO
8520 UNIVERSITY
GRN,
MIDDLETON, WI
53562-2508

MONSANTO
COMPANY
(D-U-N-S®:01-326-7070)
AKA: MONSANTO
1506 HIGHWAY 69
STE 100,
WACO, NE 68460-9130

MONSANTO
COMPANY
(D-U-N-S®:01-612-5234)
AKA: MONSANTO
3909 E CHIPPEWA
TRL,
GRANBURY, TX
76048-6010

MONSANTO
COMPANY
(D-U-N-S®:01-806-2047)
AKA: MONSANTO
503 S MAPLEWOOD
AVE,
WILLIAMSBURG, IA
52361-8621

MONSANTO
COMPANY
(D-U-N-S®:02-169-1795)
AKA: MONSANTO
721 HIGHWAY 6,
GRINNELL, IA 50112-8004

MONSANTO
COMPANY
(D-U-N-S®:03-141-8536)
AKA: MONSANTO
RT 25 N,
ULYSSES, KS 67880

MONSANTO
COMPANY
(D-U-N-S®:03-229-3644)
AKA: MONSANTO
860 BLUE GENTIAN
RD STE 175B,
SAINT PAUL, MN
55121-4402

MONSANTO
COMPANY
(D-U-N-S®:03-505-3925)
AKA: MONSANTO
2617 ANTELOPE AVE,
KEARNEY, NE 68847-3876

MONSANTO
COMPANY
(D-U-N-S®:03-859-2874)
AKA: MONSANTO
3421 STATE ROUTE
51 SOUTH,
CENTRALIA, IL 62801

MONSANTO
COMPANY
(D-U-N-S®:03-929-8526)
AKA: MONSANTO
KO RD HANAPEPE
VLY,
HANAPEPE, HI 96716

MONSANTO
COMPANY
(D-U-N-S®:04-470-2637)
AKA: MONSANTO
HWY 87 W,
DUMAS, TX 79029

MONSANTO
COMPANY
(D-U-N-S®:04-871-2538)
AKA: MONSANTO
2335N HIGGINS RD,
MORRIS, IL 60450-9608

MONSANTO
COMPANY
(D-U-N-S®:04-855-3390)
AKA: MONSANTO
3000 WESTOWN
PKWY,
WEST DES MOINES,
IA 50268-1320

MONSANTO
COMPANY
(D-U-N-S®:04-871-8006)
AKA: MONSANTO
112 S CAMPBELL
BLVD,
HAUBSTADT, IN
47639-8162

MONSANTO
COMPANY
(D-U-N-S®:04-952-9386)
AKA: MONSANTO
432 S CHARTER ST,
MONTICELLO, IL
61856-1806

MONSANTO
COMPANY
(D-U-N-S®:05-114-8711)
AKA: MONSANTO
1200 W 20TH ST,
OKMULGEE, OK
74447-4202

MONSANTO
COMPANY
(D-U-N-S®:05-523-8229)
AKA: MONSANTO
13236 POLK ST,
OMAHA, NE 68137-4252

Branches Global

MONSANTO,IZMIR
OFISI
(D-U-N-S®:56-621-3718)
Pinarbasi Ambarlar
Sitesi, No:4 12. Blok,
Istanbul (Anatolia),
TR

MONSANTO,
LULEBURGAZ OFISI;
(D-U-N-S®:56-621-3719)
Eski Sanayi Sitesi,
No:28 Gural Petrol
Karsisi,
Istanbul (Anatolia),
TR

Monsanto Korea Inc.
(D-U-N-S®:69-000-0757)
5/F Kwanghee Bldg.,
216 Kwangheedong1-
ga, Chung-gu,
SEOUL, 121020,
KR

Subsidiaries Domestic

CEREON GENOMICS
LLC
(D-U-N-S®:00-495-8000)
45 SIDNEY ST,
CAMBRIDGE, MA
02139-4133

CORN STATES
HYBRID SERVICE
LLC;
(D-U-N-S®:00-530-4613)
3302 SE
CONVENIENCE BLVD,
ANKENY, IA 50021-9424

DELTA AND PINE
LAND COMPANY;
(D-U-N-S®:00-696-4845)
1 COTTON ROW,
SCOTT, MS 38772-9700

CHANNEL BIO, LLC
(D-U-N-S®:03-507-2446)
3820 N 56TH ST,
LINCOLN, NE 68504-1705

SEMINIS VEGETABLE
SEEDS, INC.;
(D-U-N-S®:04-116-2140)
2700 CAMINO DEL
SOL,
OXNARD, CA 93030-7967

CALGENE, LLC
(D-U-N-S®:04-714-0280)
1920 5TH ST,

MONSANTO CHOICE
GENETICS, INC.;
(D-U-N-S®:05-542-9682)

WESTBRED, LLC
(D-U-N-S®:15-612-8142)
AKA: FOMERLY

AMERICAN SEEDS,
INC.
(D-U-N-S®:17-077-6921)

INTERSTATE SEED
COMPANY INC;
(D-U-N-S®:80-15-0025)



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AKA: MONSANTO
800 N LINDBERGH
BLVD,
SAINT LOUIS, MO
63141-7843

WESTERN PLANT
BREEDERS
81 TIMBERLINE DR,
BOZEMAN, MT 59718-
6994

800 N LINDBERGH
BLVD,
SAINT LOUIS, MO
63141-7843

304 CENTER ST,
WEST FARGO, ND
58078-1209

SEMINIS, INC.
(D-U-N-S®:94-836-
5861)
2700 CAMINO DEL
SOL,
OXNARD, CA 93030-
7967

PRECISION
PLANTING, INC.
(D-U-N-S®:01-126-
4294)
23207 TOWNLINE RD,
TREMONT, IL 61568-
8725

P4 PRODUCTION,
L.L.C.
(D-U-N-S®:12-368-
2390)
1853 HIGHWAY 34,
SODA SPRINGS, ID
83276-5227

MONSANTO AGRI
SERVICES LLC;
(D-U-N-S®:01-947-
2267)
1860 INDUSTRIAL
CIR,
LONGMONT, CO
80501-6559

BEEOLOGICS, LLC
(D-U-N-S®:01-135-
6992)
11800 SW 77TH AVE,
MIAMI, FL 33156-4565

MONSANTO CO
(D-U-N-S®:03-346-
9967)
AKA: MONSANTO
1853 HIGHWAY 34,
SODA SPRINGS, ID
83276-5227

DIVERGENCE, INC.
(D-U-N-S®:07-266-
9828)
800 N LINDBERGH
BLVD,
SAINT LOUIS, MO
63167-1000

FIELDER'S CHOICE,
LTD.
(D-U-N-S®:61-297-
8382)
AKA: FIELDERS
CHOICE DIRECT
800 S GILBERT ST,
DANVILLE, IL 61832-
7132

Subsidiaries Global

Monsanto Canada Inc
(D-U-N-S®:20-565-
7448)
1 Research Way Suite
900,
WINNIPEG,
MANITOBA R3T 6E3,
CA

MONSANTO UK LTD
(D-U-N-S®:22-039-
6571)
Cambridge, CB23
6DW,
GB

MONSANTO
HOLLAND BV
(D-U-N-S®:27-692-
1447)
1 RUE JACQUES
MONOD,
BRON, 69500,
FR

Monsanto S.A./N.V.
Belgien;
(D-U-N-S®:30-583-
5378)
Weidekampsgade 6,
c/o Deloitte,
COPENHAGEN, 2300,
DK

Monsanto Crop
Sciences Denmark A/S;
(D-U-N-S®:30-608-
8456)
Tuborg Havnevej 19,
c/o Rnne & Lundgren,
HELLERUP, 2900,
DK

Monsanto Europe NV
(D-U-N-S®:37-483-
8506)
Scheldelaan 460Hav
627,
Antwerp, 2040,
BE

MONSANTO SAS
(D-U-N-S®:50-165-
3179)
EDEN PARK
BATIMENT B,
1 RUE BUSTER
KEATON,
ST PRIEST, 69800,
FR

MONSANTO SOUTH
AFRICA (PTY) LTD;
(D-U-N-S®:53-848-
2662)
CORNER OF
FOURWAYS BLVD &
ROOS STREET,
Johannesburg, 2055,
ZA

MONSANTO VIETNAM
(D-U-N-S®:55-528-
8393)
Room 140, 14th Floor,
Sun Wah Tower,,
District 1,
Ho Chi Minh,
VN

MONSANTO
COMPANY
(D-U-N-S®:56-547-
2243)
National Seed,
Lilongwe 3, 30050,
MW

MONSANTO
COMPANY
(D-U-N-S®:56-547-
2297)
Plot No. 06 Block A,
Esso Road,
Arusha, 1280,
TZ

MONSANTO
COMPANY
(D-U-N-S®:56-547-
3696)
1st Floor, M.T.K.
Building Plot 41/43
Nasser Road,
KAMPALA, 434,
UG

Monsanto Ukraine
Limited Liability
Company;
(D-U-N-S®:56-551-
0302)
Building B, 7th floor,
10/14 Radischeva
street,
Kyiv, 03680,
UA

Monsanto Produccion y
Servicios, S.A. de C.V.;
(D-U-N-S®:58-990-
9621)
Prolg. Paseo de la
Reforma No. 1015,
MEXICO CITY, 01376,
MX

Monsanto Crop
Sciences Sweden AB;
(D-U-N-S®:63-195-
7995)
Ekbacksvägen 28,
Bromma, 168 69,
SE

MONSANTO
(MALAYSIA)
SDN.BHD.;
(D-U-N-S®:65-208-
6281)
Plo 211 Jalan Emas 1,
Pasir Gudang Industrial
Estate,
PASIR GUDANG,
81700,
MY

Monsanto Far East
Limited
(D-U-N-S®:68-622-
0716)
Rm 1205 12/F Sino
Plaza,
255 Gloucester Rd,
CAUSEWAY BAY,
HK

MONSANTO JAPAN
LIMITED
(D-U-N-S®:69-621-
6188)
4-10-10, GINZA,
GINZASANO BLDG.
8F.,
CHUO-KU, 104-0061,
JP

MONSANTO
PHILIPPINES
INCORPORATED;
(D-U-N-S®:71-869-
5240)
7th FloorAyala Life-
FGU Center,
Alabang-Zapote Road
corner Acacia Avenue,
MUNTINGLUPA, 1770,
PH

MONSANTO PHILS
INC
(D-U-N-S®:71-873-
3769)
7th FloorAyala Life FGU
Center,
Alabang Zapote Road,
Madrigal Business Park,
MUNTINGLUPA, 1799,
PH

MONAGRO KIMIA, PT
(D-U-N-S®:72-886-
9624)
Wisma Pondok Indah
Fl. 6th,
Jl. Sultan Iskandar
Muda Kav. V-TA,
JAKARTA,

Monsanto Comercial,
S.A. de C.V.;
(D-U-N-S®:81-093-
9041)
Prolongacin Paseo de
La Reforma No. 1015,
Piso 22,
MEXICO CITY, 01376,

Semillas y
Agroproductos
Monsanto, S.A. de
C.V.;
(D-U-N-S®:81-139-
1903)
Prol. Paseo de la
Reforma No. 1015,

Monsanto Venezuela
CA
(D-U-N-S®:88-555-
3909)
Av Venezuela Torre
Clemente. Mezanina A,
CARACAS,
VE

Monsanto Technologies
India Limited;
(D-U-N-S®:91-534-
5128)
308, Sophias Choice,
No 7,
BANGALORE, 56000
IN



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ID

MX

Torre A Piso 21,
MEXICO CITY, 01376,
MX

This list is limited to the first 25 branches, subsidiaries, divisions and affiliates, both domestic and international. Please use the Global Family Linkage Link above to view the full listing.

Financial Statements

Statement Update

Interim Consolidated statement dated MAY 31 2013 (in thousands):

Assets	USD	Liabilities	USD
Current Assets		Current Liabilities	
Cash	\$2,921,000	Accts Pay	\$745,000
Accts Rec	3,610,000	Short-Term Debt	169,000
Inventory	2,884,000	Accruals	2,181,000
Mktble Securities	143,000	Taxes	397,000
Miscellaneous Receivables	812,000	Deferred Revenues	322,000
Deferred Tax Assets	574,000	Total Current Liabilities	3,814,000
Other Curr Assets	197,000		
Total Current Assets	11,141,000		
Non Current Assets		Non Current Liabilities	
Fixt & Equip	4,467,000	Long-Term Debt	2,054,000
Goodwill	3,510,000	Other Liabilities	420,000
Other Intangible Assets-Net	1,225,000	L.T. Liab-Other	1,146,000
Deferred Tax Assets	518,000	Def. Credits/Income	167,000
Other Assets	818,000	COMMON STOCK	6,000
Total Assets	21,679,000	ADDIT. PD.-IN CAP	10,743,000
		TREASURY STOCK	(3,623,000)
		RETAINED EARNINGS	7,865,000
		ADJUSTMENTS	(913,000)
		Total Liabilities & Net Worth	21,679,000

As of 06/28/2013

From SEP 01 2012 to MAY 31 2013 sales \$12,659,000,000; cost of goods sold \$5,930,000,000. Gross profit \$6,729,000,000; operating expenses \$2,870,000,000. Operating income \$3,859,000,000; other income \$86,000,000; other expenses \$158,000,000; net income before taxes \$3,787,000,000; Federal income tax \$1,023,000,000; net income \$2,764,000,000.

Statement Source

Statement obtained from Securities And Exchange Commission. Prepared from books without audit.

Fixed assets shown net less \$4,775,000,000 depreciation.

Explanations

The net worth of this company includes intangibles; Other Assets consist of receivables-net and other assets; Other Long Term Liabilities consist of postretirement liabilities, deferred tax liabilities and environmental & litigation liabilities; Adjustments consists of accumulated other comprehensive loss and noncontrolling interest.

Three Years Comparative Statement

Key Business Ratios (Based on 14 establishments)

	Fiscal Consolidated Aug 31 2011 USD (000s omitted)	Fiscal Consolidated Aug 31 2012 USD (000s omitted)	Interim Consolidated Nov 30 2012 USD (000s omitted)	This Business	Industry Median	Industry Quartile
Curr Assets	\$8,809,000	\$9,658,000	\$12,060,000			
Curr Liabs	4,729,000	4,221,000	6,161,000			
Profitability						
Return on Sales				21.8	5.1	1



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Current Ratio	1.86	2.29	1.96	Return on Net Worth	UN	16.1	UN
Working Capital	4,080,000	5,437,000	5,899,000	Short Term Solvency			
Other Assets	11,035,000	10,566,000	10,477,000	Current Ratio	2.9	1.9	1
Worth	11,716,000	12,036,000	12,465,000	Quick Ratio	1.7	0.9	1
Sales	11,822,000	13,504,000		Efficiency			
Long Term Liab	3,399,000	3,967,000	3,911,000	Assets Sales	UN	63.4	UN
Net Profit (Loss)	1,659,000	2,093,000		Sales / Net Working Capital	1.7	4.1	4
				Utilization			
				Total Liabs / Net Worth	UN	69.9	UN

As of 05/31/2013

Most Recent Financial Statement

Interim Consolidated statement dated NOV 30 2012 (in thousands):

Assets	USD	Liabilities	USD
Current Assets		Current Liabilities	
Cash	\$4,637,000	Accts Pay	\$785,000
Accts Rec	2,168,000	Short-Term Debt/Long-Term Debt	26,000
Inventory	3,571,000	Accruals	1,728,000
Mktble Securities	310,000	Taxes	68,000
Miscellaneous Receivable	700,000	Deferred Revenues	2,843,000
Deferred Tax Assets	513,000	Customer Payable	8,000
Other Curr Assets	161,000	Other Curr Liabs	703,000
Total Current Assets	12,060,000	Total Current Liabilities	6,161,000
Non Current Assets		Non Current Liabilities	
Fixt & Equip	4,348,000	Long-Term Debt	2,054,000
Goodwill	3,447,000	L.T. Liab-Other	1,639,000
Other Intangible Assets-Net	1,210,000	Def. Credits/Income	218,000
Deferred Tax Assets	552,000	COMMON STOCK	6,000
Other Assets	920,000	ADDIT. PD.-IN CAP	10,437,000
Total Assets	22,537,000	TREASURY STOCK	(3,072,000)
		RETAINED EARNINGS	5,876,000
		ADJUSTMENTS	(782,000)
		Total Liabilities & Net Worth	22,537,000

As of 01/29/2013

From SEP 01 2012 to NOV 30 2012 sales \$2,939,000,000; cost of goods sold \$1,542,000,000. Gross profit \$1,397,000,000; operating expenses \$888,000,000. Operating income \$509,000,000; other income \$23,000,000; other expenses \$68,000,000; net income before taxes \$464,000,000. Federal income tax \$126,000,000. Net income \$349,000,000. Income From Disc Operations \$11,000,000.

Statement Source

Statement obtained from Securities And Exchange Commission. Prepared from books without audit.

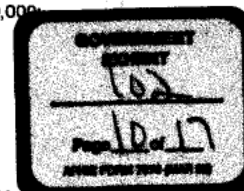
Accounts receivable shown net less \$140,000,000 allowance. Fixed assets shown net less \$4,584,000,000 depreciation.

Explanations

The net worth of this company includes intangibles. Other assets consist of long-term receivables-net and other assets; other long term liabilities consist of postretirement liabilities, deferred tax liabilities, long-term-environmental & litigation liabilities and other liabilities; adjustments consist of accumulated other comprehensive loss and non-controlling interest.

The report was updated using information the company filed with the Securities and Exchange Commission.

Although the financial statements reflect a strong financial condition, an overall good composite credit appraisal has been assigned due to occasional reports of slow trade payments that are contained in the D&B files.



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Indicators**Public Filings Summary**

The following data includes both open and closed filings found in D&B's database on this company

Record Type	No. of Records	Most Recent Filing Date
Judgment	0	
Lien	3	01/19/2011
Suit	3	09/28/2011
UCC	411	04/16/2013

Public Filings

* Bankruptcy * Judgment * Lien * Suit * UCC

The following Public Filing data is for information purposes only and is not the official record. Certified copies can only be obtained from the official source.

Full Filings**Suits**

Amount	\$9,992	Latest Info Received	12/02/2011
Status	Pending	CASE NO.	CC2011193488
Where Filed	MARICOPA COUNTY JUSTICE COURT/MCDOWELL MOUNTAIN, PHOENIX, AZ	Status Attained	09/28/2011
Plaintiff	ALLSTATE CORP	Date Filed	09/28/2011
Defendant	MONSANTO CO		
Cause	Breach of contract		

Status	Pending	Latest Info Received	10/03/2008
Where Filed	SHELBY COUNTY GENERAL SESSIONS COURT, MEMPHIS, TN	CASE NO.	1307434
Plaintiff	NATIONAL BANKERS TRUST CORPORATION	Status Attained	08/22/2008
Defendant	MONSANTO CO	Date Filed	08/22/2008
Cause	OTHER		

Status	Pending	Latest Info Received	06/06/2008
Where Filed	CALHOUN COUNTY CIRCUIT COURT, ANNISTON, AL	DOCKET NO.	CV2008000248
Plaintiff	ROSCOE LOUIS HOLLOWAY	Status Attained	05/28/2008
Defendant	MONSANTO COMPANY AND OTHERS	Date Filed	05/28/2008

If it is indicated that there are defendants other than the report subject, the lawsuit may be an action to clear title to property and does not necessarily imply a claim for money against the subject.

Liens

Amount	\$1,060	Latest Info Received	03/04/2011
Status	Open	Type	State Tax
Where Filed	RICHLAND COUNTY REGISTER OF DEEDS, COLUMBIA, SC	Status Attained	01/19/2011
Filed By	ST OF SOUTH CAROLINA	Date Filed	01/19/2011
against	MONSANTO CO	BOOK/PAGE	1660/2527

Amount	\$527	Latest Info Received	04/16/2008
Status	Open	Type	State Tax
Where Filed	HINDS COUNTY CIRCUIT COURT - JACKSON, JACKSON, MS	Status Attained	09/12/2007
Filed By	STATE OF MISSISSIPPI	Date Filed	09/12/2007
against	MONSANTO CO		



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Status	Open	DOCKET NO.	92/338291
Where Filed	JEFFERSON COUNTY DEEDS AND RECORDS, LOUISVILLE, KY	Latest Info Received	04/04/2008
Filed By	COMMONWEALTH OF KENTUCKY	Type	State Tax
against	MONSANTO COMPANY	Status Attained	01/13/2006
		Date Filed	01/13/2006
		BOOK/PAGE	860/665

A lienholder can file the same lien in more than one filing location. The appearance of multiple liens filed by the same lienholder against a debtor may be indicative of such an occurrence.

UCC Filings

Collateral	Negotiable instruments and proceeds - Account(s) and proceeds - Fixtures and proceeds - Communications equipment and proceeds - and OTHERS	Latest Info Received	01/05/2011
Filing No.	2010 4473892	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	12/17/2010
Secured Party	RBS ASSET FINANCE, INC., CHICAGO, IL		
Debtor	MONSANTO COMPANY		
Collateral	Inventory and proceeds - Equipment and proceeds	Latest Info Received	06/07/2012
Filing No.	2012 1862459	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	05/15/2012
Secured Party	THE BOELTER COMPANIES, INC, WAUKESHA, WI		
Debtor	MONSANTO COMPANY		
Filing No.	2012 3241694	Latest Info Received	10/12/2012
Original UCC Filed Date	05/15/2012	Type	Termination
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	08/21/2012
Secured Party	THE BOELTER COMPANIES, INC, WAUKESHA, WI	Original Filing No.	2012 1862459
Debtor	MONSANTO COMPANY		
Collateral	Inventory and proceeds - Account(s) and proceeds - Chattel paper and proceeds - General intangibles(s) and proceeds - and OTHERS	Latest Info Received	09/22/2011
Filing No.	2011 3382457	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	08/31/2011
Secured Party	KUBOTA TRACTOR CORPORATION, TORRANCE, CA		
Debtor	MONSANTO COMPANY		
Collateral	Leased Inventory - Leased Building(s) - Leased Equipment	Latest Info Received	01/03/2013
Filing No.	2012 4711661	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	12/06/2012
Secured Party	CITIZENS STATE BANK, ROSEAU, MN KINETIC LEASING, INC., FARGO, ND		
Debtor	MONSANTO COMPANY, ST LOUIS, MO		
Collateral	Account(s) including proceeds and products - Chattel paper including proceeds and products - General intangibles(s) including proceeds and products - Leased Equipment including proceeds and products	Latest Info Received	11/24/2008
Filing No.	2008 3578588	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	10/23/2008
Secured Party	RBS ASSET FINANCE, INC., CHICAGO, IL		
Debtor	MONSANTO COMPANY		



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Collateral	Account(s) including proceeds and products - Chattel paper including proceeds and products - General intangibles(s) including proceeds and products - Leased Vehicles including proceeds and products	Latest Info Received	10/16/2008
Filing No.	2008 3174859	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	09/16/2008
Secured Party	RBS ASSET FINANCE, INC., CHICAGO, IL		
Debtor	MONSANTO COMPANY		
Collateral	Account(s) including proceeds and products - Equipment including proceeds and products - Chattel paper including proceeds and products - General intangibles(s) including proceeds and products	Latest Info Received	10/09/2008
Filing No.	2008 3053947	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	09/03/2008
Secured Party	RBS ASSET FINANCE, INC., CHICAGO, IL		
Debtor	MONSANTO COMPANY		
Collateral	Account(s) including proceeds and products - Chattel paper including proceeds and products - General intangibles(s) including proceeds and products - Leased Equipment including proceeds and products	Latest Info Received	10/16/2008
Filing No.	2008 3130158	Type	Amendment
Original UCC Filed Date	09/03/2008	Date Filed	09/16/2008
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Original Filing No.	2008 3053947
Secured Party	RBS ASSET FINANCE, INC., CHICAGO, IL		
Debtor	MONSANTO COMPANY		
Collateral	Account(s) including proceeds and products - Chattel paper including proceeds and products - General intangibles(s) including proceeds and products - Leased Equipment including proceeds and products	Latest Info Received	09/10/2008
Filing No.	2008 2734919	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	08/11/2008
Secured Party	RBS ASSET FINANCE, INC., CHICAGO, IL		
Debtor	MONSANTO COMPANY		
Collateral	Account(s) including proceeds and products - Chattel paper including proceeds and products - General intangibles(s) including proceeds and products - Leased Equipment including proceeds and products	Latest Info Received	07/25/2008
Filing No.	2008 2142659	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	06/23/2008
Secured Party	RBS ASSET FINANCE, INC., CHICAGO, IL		
Debtor	MONSANTO COMPANY		
Collateral	Account(s) including proceeds and products - Chattel paper including proceeds and products - General intangibles(s) including proceeds and products - Leased Equipment including proceeds and products	Latest Info Received	07/25/2008
Filing No.	2008 2142642	Type	Original
Where Filed	SECRETARY OF STATE/UCC DIVISION, DOVER, DE	Date Filed	06/23/2008
Secured Party	RBS ASSET FINANCE, INC., CHICAGO, IL		
Debtor	MONSANTO COMPANY		

The public record items contained in this report may have been paid, terminated, vacated or released prior to the date this report was printed. Additional UCC and SLJ filings for this company can be found by conducting a more detailed search in our Public Records Database.

Paydex

Business Information Report

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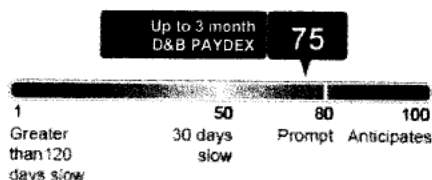


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D&B PAYDEX®

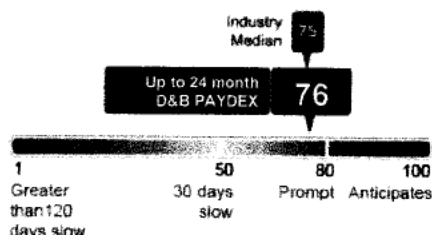
Shows the D&B PAYDEX scores as calculated up to 3 months and up to 24 months of payment experiences.

Up to 3 month D&B PAYDEX



When weighted by dollar amount, payments to suppliers average 8 Days Beyond Terms. Based on payments collected over last 3 months.

Up to 24 month D&B PAYDEX



When weighted by dollar amount, payments to suppliers average 6 days beyond terms. Based on payments collected up to 24 months.

When weighted by dollar amount, the industry average is 8 DAYS BEYOND terms.

High risk of late payment (average 30 to 120 days beyond terms)

Medium risk of late payment (average 30 days or less beyond terms)

Low risk of late payment (average prompt to 30+ days sooner)

Payment Trend	unchanged *	Total Payment Experiences for the HQ	794	Highest Now Owing	\$20,000,000
Payments Within Terms	74%	Total Placed for Collection	1	Highest Past Due	\$750,000
Average High Credit	\$205,058	Largest High Credit	\$30,000,000		

* compared to payments three months ago

Payment Summary

The Payment Summary section reflects payment information in D&B's file as of the date of this report.

There are 794 payment experiences in D&B's file, with 541 experiences reported during the last three month period. The highest Now Owes on file is \$20,000,000. The highest Past Due on file is \$750,000.

Top 10 Industries

Industries	Total Received	Total Amounts	Largest High Credit	Within Terms (%)	Days Slow (%)			
					0-30	31-60	61-90	90+
Nonclassified	42	\$37,772,850	\$30,000,000	94	6	0	0	0
Whol electrical equip	18	1,135,750	900,000	93	5	2	0	0
Ret mail-order house	13	1,670,350	1,000,000	51	49	0	0	0
Railroad	11	2,440,250	1,000,000	79	21	0	0	0
Mfg organic chemicals	5	28,600,000	20,000,000	86	14	0	0	0
Petroleum refining	5	38,200,000	15,000,000	90	10	0	0	0
Holding company	5	8,050,000	7,000,000	56	44	0	0	0
Crops-plant/protect	3	3,040,000	2,000,000	99	1	0	0	0
Mfg plastics/resins	2	2,095,000	2,000,000	2	96	2	0	0
Mfg synthetic rubber	1	2,000,000	2,000,000	100	0	0	0	0
OTHER INDUSTRIES	612	17,716,700	1,000,000	72	21	2	4	1

Other Payment Categories

Category	Total Received	Total Dollar Amounts	Largest High Credit
Cash Experiences	54	\$21,250	\$10,000
Payment record unknown	21	86,600	20,000



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Unfavorable comments

1

500

500

Placed for Collection

1

0

0

Detailed Payment History

Date Reported	Paying Record	High Credit	Now Owes	Past Due	Selling Terms	Last Sale within(months)
July 2013	Ppt	\$250	\$0	\$0	N/A	6-12
	Ppt-Slow 30	100,000	100,000	10,000	N/A	1
June 2013	Disc-Ppt	7,500	2,500	0	N/A	1
	Ppt	0	0	0	N/A	1
	Ppt	0	500	0	N/A	1
	Ppt	2,000,000	0	0	N/A	1
	Ppt	900,000	900,000	100,000	N60	1
	Ppt	300,000	70,000	0	2 10 N45	1
	Ppt	100,000	40,000	5,000	N30	1
	Ppt	85,000	30,000	0	N/A	1
	Ppt	40,000	35,000	0	2 10 N45	1
	Ppt	35,000	30,000	0	N/A	1
	Ppt	25,000	5,000	50	N/A	1
	Ppt	20,000	1,000	0	2 10 N45	1
	Ppt	15,000	5,000	0	2 10 N45	1
	Ppt	10,000	0	0	N/A	6-12
	Ppt	10,000	7,500	0	N/A	1
	Ppt	7,500	5,000	0	N/A	1
	Ppt	7,500	7,500	0	N30	1
	Ppt	5,000	5,000	0	N/A	1
	Ppt	5,000	0	0	N30	6-12
	Ppt	5,000	1,000	0	N/A	1
	Ppt	2,500	0	0	N/A	6-12
	Ppt	2,500	0	0	N/A	6-12
	Ppt	2,500	2,500	0	N/A	1
	Ppt	2,500	0	0	N/A	2-3
	Ppt	2,500	0	0	N30	2-3
	Ppt	2,500	0	0	N60	6-12
	Ppt	2,500	0	0	N/A	6-12
	Ppt	2,500	1,000	0	N/A	1
	Ppt	2,500	2,500	0	N30	1
	Ppt	1,000	1,000	0	N/A	1
	Ppt	1,000	1,000	0	N/A	1
	Ppt	1,000	0	0	N/A	1
	Ppt	1,000	100	0	N/A	1
	Ppt	1,000	0	0	N30	4-5
	Ppt	1,000	0	0	N30	1
	Ppt	750	0	0	N30	6-12
	Ppt	500	100	0	N30	1
	Ppt	250	0	0	N/A	1
	Ppt	250	250	0	Lease Agreeemnt	1
	Ppt	250	0	0	Lease Agreeemnt	1
	Ppt	250	0	0	N30	



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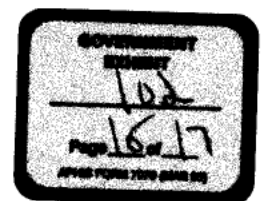
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Ppt	50	50	0	N/A	1
Ppt	50	50	0	N30	1
Ppt	50	50	0	N/A	1
Ppt	0	0	0	N30	1
Ppt	0	0	0	N/A	1
Ppt-Slow 15	3,000,000	0	0	N/A	6-12
Ppt-Slow 15	7,500	7,500	0	N/A	1
Ppt-Slow 30	85,000	5,000	5,000	N/A	4-5
Ppt-Slow 30	20,000	10,000	0	N/A	2-3
Ppt-Slow 30	10,000	10,000	10,000	N/A	1
Ppt-Slow 30	7,500	7,500	0	2 30 N30	1
Ppt-Slow 30	2,500	500	0	N/A	1
Ppt-Slow 30	2,500	0	0	N/A	2-3
Ppt-Slow 30	2,500	1,000	100	N/A	1
Ppt-Slow 30	2,500	2,500	2,500	N45	1
Ppt-Slow 30	500	250	0	Lease Agreement	1
Ppt-Slow 60	200,000	100,000	100,000	N/A	1
Ppt-Slow 60	40,000	1,000	750	N/A	1
Ppt-Slow 60	25,000	7,500	0	N/A	1
Ppt-Slow 60	7,500	7,500	100	N/A	1
Ppt-Slow 90	2,500	2,500	1,000	N/A	1
Ppt-Slow 90+	55,000	25,000	25,000	N/A	6-12
Ppt-Slow 90+	500	0	0	N/A	6-12
Slow 15	10,000	0	0	N/A	2-3
Slow 15	1,000	0	0	N15	6-12
Slow 15	250	250	250	N/A	
Slow 30	10,000	0	0	N/A	1
Slow 30	2,500	0	0	N/A	6-12
Slow 30	2,500	750	0	N/A	1
Slow 40	250	0	0	N/A	4-5
Slow 60	750	0	0	N/A	4-5
Slow 60-90	1,000	750	750	N/A	1
Slow 30-90	1,000	750	750	N/A	2-3
Slow 30-180	5,000	500	0	N/A	1
(078)	0	0	0	Sales COD	1
May 2013 Ppt	15,000	50	0	N/A	1
Slow 40	7,500	2,500	2,500	N/A	1

Lines shown in red are 30 or more days beyond terms

Payment experiences reflect how bills are met in relation to the terms granted. In some instances payment beyond terms can be the result of disputes over merchandise, skipped invoices etc.

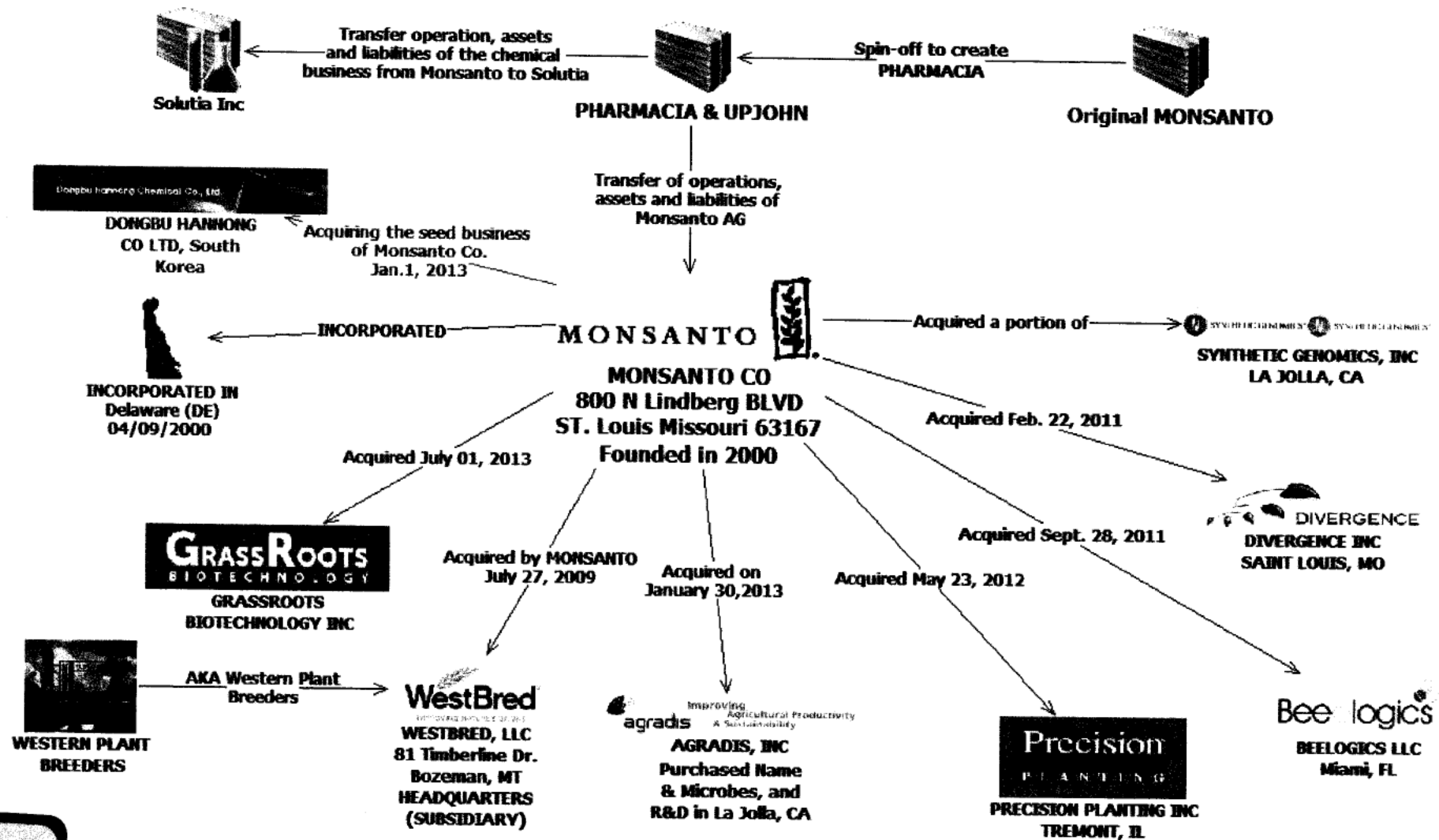
Each experience shown is from a separate supplier. Updated trade experiences replace those previously reported.



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MONSANTO COMPANY



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USDA APHIS

(via e-mail) on July 17, 2013.

Declaration of (b) (4)

I declare that my name is (b) (4), I am over the age of eighteen and I am fully competent to make this declaration. I know each of the facts set forth herein to be true based on personal firsthand knowledge:

I am currently employed as a Senior Investigator with the United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS), Investigative and Enforcement Services (IES). I have been employed in this position for approximately (b) (6), (b) (7) years. My business address is USDA, APHIS, IES, 2150 Centre Avenue, Bldg. (b) (6), (b) (7)(C) Fort Collins, CO 80526. My office telephone number is (b) (6), (b) (7) and my cell phone number is (b) (6), (b) (7)

On 12/03/13 through 12/13/13, Sharon M. Talley, Ph.D., Biological Scientist, Western Compliance Assurance Branch USDA - APHIS - BRS (Dr. Talley) and I travelled to Monsanto Company, 800 North Lindbergh Blvd., St. Louis, Missouri 63167, 314-694-1000.

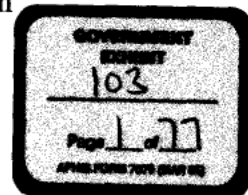
Dr. Talley and I were at Monsanto to review field test books from (b) (4) and (b) (4) both of whom were (b) (4) during the time of the MON71800 testing (b) (4). Also during our visit to Monsanto we obtained compliance reports of WestBreds work with the MON71800 test plots.

Monsanto provided the compliance reports from the eleven MON71800 notifications in which (b) (4) were involved.

I reviewed all eleven compliance reports looking for any compliance issues, which may have led to the release of MON71800 into the environment. After the review, I can not find a link between the test plot research and the release of MON71800 in the affected field in Eastern Oregon in 2013.

During the review of the compliance reports, I found issues of noncompliance.

- The precise locations of all GE field test sites planted in the United States are not always



known. APHIS does not follow up with all notification holders to find out exactly where the fields have been planted or if they have been planted at all.

- In some cases, APHIS may only be aware of the State and county where an applicant plans to conduct a field test.

- At the conclusion of the field test, APHIS does not require permit holders to report on the final disposition of GE harvests. There are instances where the notification holders do not report volunteer monitoring for the prescribed time frame.

These issues were also addressed in an OIG report from December 2005.

I found nothing which would lead me to connect these noncompliance issues the contamination of the Oregon farmers field where the MON71800 was discovered in 2013.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. This declaration was executed on January 22, 2014.

(b) (4)

(b) (4)

Investigator

USDA-APHIS-IES





U.S. Department of Agriculture



Office of Inspector General
Southwest Region

Audit Report

Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits

Audit 50601-8-Te
December 2005

OR120018_BR_002975





UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL
Washington, D.C. 20250



DEC 8 2005

REPLY TO

ATTN OF: 50601-8-Te

TO: W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

ATTN: William J. Hudnall
Deputy Administrator for Marketing and
Regulatory Programs - Business Services

FROM: Robert W. Young /s/
Assistant Inspector General for Audit

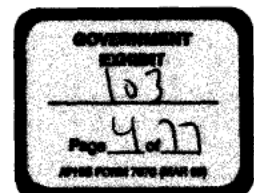
SUBJECT: Controls Over Issuance of Genetically Engineered Organism Release Permits

This report presents the results of the subject audit. Your written response to the draft report, dated November 2, 2005, is included in its entirety as exhibit A with excerpts and the Office of Inspector General's (OIG) position incorporated into the relevant Findings and Recommendations sections of the report.

Based on your response, we accepted management decision on Recommendation 25. Please follow Departmental and your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer, Director, Planning and Accountability Division (OCFO/PAD).

Although we agree with most of the other planned corrective actions, we could not accept management decision on all other recommendations. Documentation and actions needed to reach management decisions for these recommendations are described in the OIG Position section of the report.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementing those recommendations for which management decision has not been reached. Please note that the regulation requires a management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management



OR120018_BR_002977

W. Ron DeHaven

2

decision to prevent being listed in the Department's annual Performance and Accountability Report.

We appreciate your timely response and the courtesies and cooperation extended to us by members of your staff during the audit.



OR120018_BR_002979

Executive Summary

Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits (Audit Report 50601-8-Te)

Results in Brief

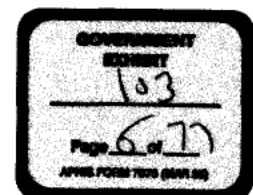
The number of approved applications to field test genetically engineered (GE) crops in the United States has increased significantly since 1986, when the Department began regulating experimental GE plants. Since that time, the U.S. Department of Agriculture (USDA) has approved over 10,600 applications for more than 49,300 field sites. Biotechnology companies are investing millions of dollars to develop new GE plants, some with the goal of commercializing them for use as food, feed, industrial compounds, and medicines. The rapid growth of agricultural biotechnology, and its prominent position in the public eye, increases USDA's responsibility to ensure that regulated GE plants, including their pollen and seeds, do not persist in the environment. However, as the number of approved applications to field test new GE plants continues to rise, we are concerned that the Department's efforts to regulate those crops have not kept pace.

To evaluate the Animal and Plant Health Inspection Service's (APHIS) controls over releases and movements of regulated GE plants, we visited 91 field test sites in 22 States that were either planted or harvested. We inspected the sites for compliance with APHIS' requirements for the growing or postharvest season. We found that APHIS, the USDA agency that oversees biotechnology regulatory functions for the Department, needs to strengthen its accountability for field tests of GE crops. In fact, at various stages of the field test process—from approval of applications to inspection of fields—weaknesses in APHIS regulations and internal management controls increase the risk that regulated genetically engineered organisms (GEO) will inadvertently persist in the environment before they are deemed safe to grow without regulation.

Accountability for GE Crops Needs Improvement

Depending on the nature of the GE crop, APHIS authorizes field tests through two methods: permits and notifications. For field tests of high-risk GE crops, such as those designed to produce pharmaceutical and industrial compounds, APHIS issues permits. For GE crops that APHIS considers low-risk based on its scientific experience with the plants, applicants can use the more streamlined notification process. We found, however, that APHIS lacks basic information about the field test sites it approves and is responsible for monitoring, including where and how the crops are being grown, and what becomes of them at the end of the field test.

- Of primary concern, the precise locations of all GE field test sites planted in the United States are not always known. After authorizing field tests,



APHIS does not follow up with all permit and notification holders to find out exactly where the fields have been planted or if they have been planted at all. In some cases, APHIS may only be aware of the State and county where an applicant plans to conduct a field test. Without knowing the locations of all planted field test sites, including their global positioning system (GPS) coordinates, APHIS cannot effectively monitor permit and notification holders' compliance with field test requirements. In January 2005, APHIS issued a memorandum that requested notification holders to voluntarily submit GPS coordinates or other information to identify the field test after planting.

- Before approving field tests, APHIS does not review notification applicants' containment protocols, which describe how the applicant plans to contain the GE crop within the field test site and prevent it from persisting in the environment. Instead, APHIS allows notification holders to provide the protocols verbally if their field test sites are selected for inspection. Since notifications comprise the vast majority of field test authorizations, this policy undermines both the field test approval and inspection processes.
- At the conclusion of the field test, APHIS does not require permit holders to report on the final disposition of GE pharmaceutical and industrial harvests, which are modified for nonfood purposes and may pose a threat to the food supply if unintentionally released. As a result, we found that two large harvests of GE pharmaceutical crops remained in storage at the field test sites for over a year without APHIS' knowledge or approval of the storage facility.

In addition, APHIS does not thoroughly document its reviews of applications in the official files. Specifically, APHIS biotechnologists do not sufficiently document their review process and scientific basis for approving initial field test applications. APHIS also does not effectively track information required during the field tests, including approved applicants' progress reports, which should contain the results of field tests, including any harmful effects on the environment. Although we noted that many permit and notification holders submit these required progress reports late or not at all, APHIS does not always follow up to obtain the information.

Weaknesses in Inspections and Enforcement

APHIS' field test inspection process can be improved in a number of areas. Inspection requirements are vague and there is a lack of coordination between the two APHIS units responsible for the inspection program, Biotechnology Regulatory Services (BRS) and Plant Protection and Quarantine (PPQ). BRS is responsible for overall management of the program, while PPQ officers perform most of the actual inspections of GE field test sites. We found that BRS does not have a formal, risk-based process for selecting individual sites



for inspection, and that PPQ does not complete all of the inspections BRS requests, including inspections of pharmaceutical and industrial crops.

For example, we found that PPQ did not inspect all pharmaceutical and industrial field test sites five times during the 2003 growing season, as APHIS has announced to the public. APHIS has also stated publicly that pharmaceutical and industrial field test sites would be inspected twice during the postharvest period, or the year following the end of the field test, during which the field must be monitored for regrowth of the GE crop. In one case, a violation at a pharmaceutical field test site in our sample went undetected because PPQ did not perform the required inspections at that site during the 2003 postharvest monitoring period.

Further contributing to the inspection problem, neither BRS nor PPQ kept track of the total number of inspections that are actually completed. Although APHIS agreed to improve its tracking of inspection reports following an Office of Inspector General (OIG) audit more than 10 years ago, the agency continued to lack an effective, comprehensive management information system to account for all inspections and their outcomes. In fact, we found 11 violations that were not recorded in BRS' compliance infractions database at the time of our audit, even though they were reported to BRS or could have been identified from information BRS already had. APHIS took administrative action on only 1 of those 11 violations.

APHIS subsequently advised us that in September 2004, it had implemented some changes in the inspection process that included an agreement between BRS and PPQ that clarified responsibility for conducting inspections. BRS also developed a methodology for selecting notifications for inspection based upon risk. However, our review of the agreement between BRS and PPQ found that it did not include inspections of nonpharmaceutical and nonindustrial permits. BRS continues to select entire permits and notifications for PPQ to inspect which may cover numerous field test sites. Consequently, BRS has no assurance that the highest risk field sites are inspected. Also, BRS initiated an interim inspection tracking system in February 2005, during our audit, but the effectiveness of this system has not been reviewed or tested by the OIG.

Even if APHIS improves its inspection process, we found that APHIS has not updated its regulations to reflect the Plant Protection Act of 2000, under which APHIS carries out its biotechnology oversight duties. Also, an Office of the General Counsel official advised us that APHIS currently does not have legislative authority to hold applicants financially responsible for costs incurred by USDA due to an unauthorized release of regulated GEOs. Because APHIS cannot require applicants to provide proof of financial responsibility before it authorizes field tests, USDA may have to bear the expense of removing GE material from the environment in the event of an unintentional release.



Inadequate Guidance for Containing GE Crops and Seeds

Finally, we found that APHIS guidance should be strengthened to prevent the persistence of GE crops outside the field test. For example, APHIS does not specify when GE crops must be destroyed, or “devitalized,” following the field test. Approved applicants sometimes allow harvested crops to lie in the field test site for months at a time, their seeds exposed to animals and the elements. Also, because APHIS has not specifically addressed the need to physically restrict edible GE crops from public access, we found a regulated edible GE crop, which had not gone through the Food and Drug Administration’s regulatory process for approval for human consumption, growing where they could easily be taken and eaten by passersby.

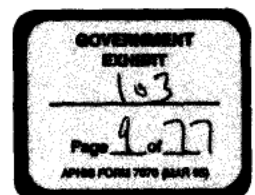
GE crops have come to play an important role in American agriculture, and many crops currently being field tested will eventually be approved as safe to grow and eat without regulation. However, while they remain under USDA’s jurisdiction, GE crops and harvests—especially those developed for pharmaceutical and industrial purposes—must be carefully regulated. Although we noted relatively few violations of existing requirements at the time of our field visits, we concluded that APHIS’ current regulations, policies, and procedures do not go far enough to ensure the safe introduction of agricultural biotechnology. To meet its strategic goals and inspire public confidence in USDA’s biotechnology regulatory program, APHIS must continue to refine and strengthen the GEO field release process.

Recommendations In Brief

To maintain accountability for regulated GE crops, APHIS needs to require more information both prior to and during the field test. Specifically, APHIS needs to:

- obtain GPS coordinates of all planted field test sites, enabling APHIS to identify where regulated GE crops are planted at any given time;
- obtain all applicants’ scientific protocols for conducting field tests;
- obtain reports on the final disposition of high-risk pharmaceutical and industrial harvests; and
- seek legislative authority to require permit applicants, based on the level of risk, to provide proof of financial responsibility, in the event of an unauthorized GEO release.

To strengthen monitoring of GE field test sites, APHIS needs to formalize its inspection process and assign and coordinate the responsibilities of BRS and PPQ. APHIS also needs to update its regulations and develop a comprehensive management information system for tracking the receipt and review of all information associated with GEO release permits and notifications.



Finally, to make sure that approved applicants take appropriate steps to prevent GE crops from proliferating outside the field test site, APHIS needs to develop guidance that specifically addresses devitalization deadlines and edible crops.

Agency Response

In its response dated November 2, 2005, APHIS officials generally agreed with OIG's recommendations and have completed or began implementing 23 of the 28 recommendations in the report.

APHIS is in the process of requiring GPS coordinates of each field site on the 28-day planting reports, requiring the reporting of the disposal of GE pharmaceutical and industrial harvest in the field report submitted 21 days prior to harvest, and obtaining a determination from the Office of the Secretary to seek legislative authority to require applicants to provide proof of financial responsibility in the event of an unauthorized GEO release.

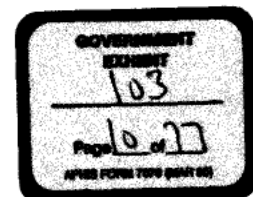
APHIS has established a Memorandum of Understanding (MOU) between BRS and PPQ to formalize inspection responsibilities, better coordinate inspections in regions, and ensure inspections are completed in a timely manner. APHIS is in the process of updating, consolidating and clarifying its regulations in regards to GE regulated field releases and incorporating provisions of the Plant Protection Act of 2000. APHIS has also designed a single management information system for tracking permit and notification inspections and field test reports.

APHIS disagreed with recommendations associated with obtaining notification applicants' scientific protocols for conducting field tests, reviewing these protocols by biotechnologists, and distributing these protocols to PPQ officers to use in conducting inspections of field sites under notification. APHIS also contends that the current system of performance-based regulatory standards for notifications is effective at protecting the American agriculture. Lastly, APHIS did not agree with developing policy guidelines for restricting public access to edible regulated crops when conducting field tests and with developing policies and procedures for selecting specific field test sites for inspection based on risk.

OIG Position

We generally concur with APHIS' response for 23 of the 28 recommendations in the report and have reached management decision on one recommendation. Actions necessary to reach management decision on the remaining recommendations are discussed in the Findings and Recommendations sections.

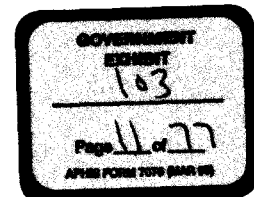
APHIS stated that its current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. We believe that these performance-based regulatory standards do not preclude submission of protocols to APHIS prior to approval of the field test. By not obtaining copies of the protocols, APHIS is relinquishing its



regulatory responsibility in favor of self-certification by the notification applicants—namely, the applicants merely certify in their notification applications that they will meet the performance standards. Further, approved protocols are important control documents that PPQ officers should receive from BRS before they perform an inspection.

Although APHIS disagreed with developing policy guidelines for restricting public access to field tests of edible regulated GE crops, APHIS' strategic plan states that its mission includes protecting human health and safety. The edible GE crops under APHIS' jurisdiction are regulated and, therefore, we believe that access should be controlled. Edible regulated GE crops cannot be grown without restrictions and should not be available even for unauthorized human consumption, while still regulated.

Although two APHIS units, BRS and PPQ, share responsibility for inspections of field test sites, BRS is responsible for the overall inspection process. However, under the current site selection process, once BRS has selected a notification or permit for inspection PPQ is then allowed to choose the specific inspection site. The National Academy of Sciences states that risks must be assessed according to the organism, trait, and environment. Thus, the environment is an important risk factor which BRS should use in the selection of field sites for inspection to ensure that the highest risk sites are always selected.



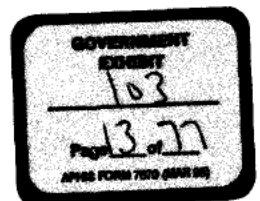
Abbreviations Used in This Report

APHIS	Animal and Plant Health Inspection Service
BBEP	Biotechnology, Biologics and Environmental Protection
BIDS	Biotechnology Integrated Database System
BRS	Biotechnology Regulatory Services
CFR	Code of Federal Regulations
EIS	Environmental Impact Statement
GE	Genetically engineered
GEO	Genetically engineered organism
GPS	Global positioning system
MOU	Memorandum of Understanding
OIG	Office of Inspector General
PPQ	Plant Protection and Quarantine
USDA	United States Department of Agriculture



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Background and Objectives

Background

Through modern biotechnology, also called genetic engineering, scientists can transform the genetic makeup and function of one organism by inserting genetic material from another organism. Agricultural biotechnology sometimes involves modifying the genetic material of one species with genes from another species—plant or nonplant—producing transgenic crops with traits not found in nature or traditional crossbreeding. For example, corn altered with a bacterial gene to produce its own insecticide has become one of the most common genetically engineered (GE) crops, along with GE soybeans and cotton. In addition to food and feed, GE crops are being developed to produce a variety of pharmaceutical and industrial substances.

In recent years, the number of acres of regulated GE plants for which the U.S. Department of Agriculture (USDA) has oversight responsibilities has increased markedly, from over 8,700 acres proposed for 1994 to over 67,000 acres proposed for 2004.

Federal Oversight of GE Crops

USDA shares responsibility for regulating biotechnology in the United States with two other Federal agencies. The Environmental Protection Agency oversees GE plants that produce their own pesticides, while the Food and Drug Administration regulates food and feed products produced from GE crops. USDA's Animal and Plant Health Inspection Service (APHIS) oversees the environmental release of new GE plants and determines whether they are safe to grow. Within APHIS, the Biotechnology Regulatory Services (BRS) unit carries out the agency's biotechnology oversight responsibilities under the Plant Protection Act of 2000,¹ which replaced the Federal Plant Pest Act and the Plant Quarantine Act.

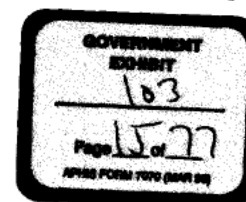
APHIS regulations² in Title 7, Code of Federal Regulations (CFR), part 340 dated January 1, 2003, focus on whether a genetically engineered organism (GEO) is a plant pest. Based on APHIS' broad definition of "plant pest,"³ almost all GEOs are considered "regulated articles"⁴ that must meet APHIS requirements for introduction into the environment. APHIS approves and monitors introductions of regulated GE crops—specifically, movements into and through the United States and field tests. After conducting a field test of a

¹ 7 United States Code 7701-7772, dated June 20, 2000

² Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests"

³ APHIS defines a plant pest as "Any living stage of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."

⁴ Organisms and products altered or produced through genetic engineering that are plant pests, unclassified organisms, or organisms whose classifications are unknown.



GEO, developers may petition APHIS, requesting that the article no longer be regulated under 7 CFR 340, dated January 1, 2003. More than 60 GEOs, such as Roundup Ready® cotton, corn, and soybeans, have received deregulated status.

Notifications and Permits: The Approval Process

Before conducting a field trial of a new GE crop, developers must apply for APHIS approval through one of two processes: notification or permit.

Notifications, the most common application method, are used to introduce certain familiar GE plants that do not present novel plant pest risks.⁵ APHIS biotechnologists determine whether the GE plants meet the six eligibility criteria for the notification approach. Specifically, to qualify for introduction under a notification, the plant must not:

- be listed as a noxious weed;
- be transformed with genetic material that has not been stably integrated into the plant genome;
- contain genes of unknown function;
- cause the production of an infectious entity, be toxic, or be intended for pharmaceutical use;
- pose a significant risk of creating any new plant virus; and
- contain genetic material from animal or human pathogens.

Under this streamlined approach, which APHIS began offering in 1993, applicants must notify APHIS at least 30 days in advance of planting. In 2004, almost 97 percent⁶ of all field trials of regulated GE crops were conducted under notifications.

In comparison to notifications, the permit process—for GE plants that do not meet the six notification eligibility criteria—requires more detailed information from the applicant. Applications for permits must be submitted at least 120 days in advance of the proposed release. Currently, permits are required for the introduction of transgenic plants that APHIS considers to pose greater safety risks—for example, those that produce pharmaceutical or industrial compounds, or those modified with human genes.

To obtain a notification, an applicant must meet certain eligibility and performance standards. The eligibility standards describe the kinds of GE plants that can be introduced in a field test. The performance standards outline general guidelines for planting, growing, harvesting, and shipping

⁵ Transgenic plants that meet the eligibility criteria specified in 7 CFR 240.3(b)1-6, dated January 1, 2003

⁶ Of 959 total approved applications, 930 were notifications.



GE crops to ensure the plant and its progeny will not persist in the environment outside the field trial.

To obtain a permit, an applicant must submit its proposed field test to be reviewed and approved by APHIS on a case-by-case basis. There are no eligibility requirements and no performance standards in the regulations for GE plants grown under permits.

Applicants for notifications and permits must develop protocols specifying how they will conduct the field trial to meet the performance standards. Protocols contain information specific to the applicant's field test, such as:

- how the applicant plans to isolate the GE crop from neighboring non-GE crops (for example, through border rows of non-GE crops);
- how the applicant plans to devitalize (destroy) or otherwise dispose of the crop at the conclusion of the field test; and
- how the applicant plans to monitor the field for volunteers (regrowth of the GE crop on the field test site following the field test).

APHIS biotechnologists review permit and notification applications and forward a summary of their review and recommendations to the biotechnology regulatory officials in the State where the field trial is to be conducted. Once those officials have approved the applications, APHIS issues the permits and notifications authorizing the field tests. According to the APHIS website, APHIS approved 45 permits and 1,929 notifications from October 2001 through September 2003. Current APHIS policy allows applicants to file one application for multiple field release sites in many different States.

Reporting, Inspections, Movements, and Infractions

For both permits and notifications, approved applicants must submit field test results to APHIS within 6 months of the completion of the field test. Depending on the nature of the permit or notification, APHIS may also require approved applicants to submit other progress reports during the field test. Reporting requirements vary depending on the acreage and location of the GE material and the company requesting the permit or notification. The following table shows some of the progress reports APHIS may require.

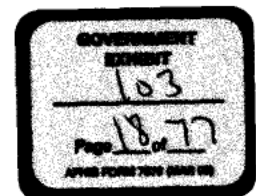


Report Type	Information Included	Required For
Planting notice	Advance notice of when and where the crop goes in the ground (7-10 days prior to planting)	Most pharmaceutical and industrial permits, some other permits
4-week/28-day report	Number of plants actually planted, GPS coordinates of the field, distance to nearest sexually compatible crop	Most pharmaceutical and industrial permits, some other permits
Harvest/termination notice	Anticipated harvest of the crop	Most pharmaceutical and industrial permits, some other permits
Monitoring report	Dates of visits to field, number and disposition of volunteers observed (if any)	Some permits
Field test data/6-month report	Methods of observation, resulting data, analysis of deleterious effects on other plants, organisms, and the environment	Required by regulation for all permits and notifications
Notice of decision not to plant	Cancellation of a planned field test site	Notifications (requested)

To ensure that approved applicants are complying with permit and notification conditions, APHIS may conduct inspections of field test sites and storage locations. APHIS' BRS works with Plant Protection and Quarantine (PPQ), a separate APHIS unit, to monitor field test sites. Although BRS biotechnologists inspect some pharmaceutical field test sites and other sites authorized under permits, PPQ officers conduct most of the inspections.

Like field tests, movements of regulated articles, such as GE seeds, are authorized under permits and notifications. Approved applicants must take measures to minimize dissemination of GEOs into the environment during movement and while in the receiving facility. BRS may arrange an inspection of the receiving facility to verify that it is adequate to prevent release of the regulated article into the environment.

Failure of applicants to submit complete and accurate information for all permit activities or to comply with performance standards may result in a fine of up to \$250,000, imprisonment for up to 5 years, or both. Failure to comply with performance standards under permit or notification conditions can also result in compliance infractions, and the applicant can be ordered to take remedial action to prevent the spread of plant pests and/or be fined.



Evolution of APHIS Biotechnology Oversight

APHIS' biotechnology regulatory operation has undergone several reorganizations since its inception in 1987. Prior to 1997, APHIS assigned biotechnology functions to its Biotechnology, Biologics and Environmental Protection (BBEP) unit. In 1997, APHIS reassigned those functions to its PPQ unit. In June of 2002, APHIS consolidated all plant biotechnology activities into the current biotechnology unit, BRS.

In 1994, USDA's Office of Inspector General (OIG) issued an audit report⁷ to BBEP. The report identified problems with APHIS' oversight of GEOs—specifically, a lack of procedures to track inspection reports and follow up on violations or potential violations. BBEP generally agreed with the recommendations to improve management and handling procedures and to create a new management information system for tracking permit and notification information.

Objectives

The objectives of our audit were to determine whether APHIS' controls provide reasonable assurance that movements and releases of GEOs in the environment are in accordance with laws, regulations, and departmental procedures, and that they are effective in minimizing the inadvertent release of GEOs in the environment. As part of our overall assessment, we evaluated APHIS' controls over the application process, management and oversight of field tests, and enforcement.

⁷ Audit Report 33099-9-Hy, dated August 1994



Findings and Recommendations

Section 1. Overall Assessment

Finding 1

APHIS Needs a More Cohesive Formal Process to Manage GEO Field Releases

As USDA's regulatory gatekeeper for GEO field tests and shipments, APHIS is tasked with establishing effective controls to prevent the inadvertent release of regulated GE material. APHIS has relied heavily on a case-by-case assessment of the risks related to each GE field release, and it has assured the public that its controls over the field test process are rigorous and effective. However, we found that APHIS' current approach is not sufficient to manage field releases of regulated GE crops. At some critical stages of the process, from the initial review and approval of applications to inspections of field test sites and enforcement activities, APHIS lacks clear, comprehensive requirements and effective internal controls to minimize the risk of inadvertent release of GEOs into the environment.

Since 1986, APHIS has authorized more than 49,300 proposed field tests of experimental GE crops. According to APHIS officials, even the agency's critics have acknowledged that no demonstrable negative environmental impacts have arisen from the field tests that have been planted. Our field test site visits indicated that developers of regulated GE crops have, on the whole, complied with APHIS' broad requirements for field tests. At the 91 sites⁸ we visited, we found 13 instances of noncompliance at 11 sites. We also learned of two additional violations at sites we did not visit. The only widespread violation we identified pertained to 193 movements of GE seeds, which APHIS allowed to be shipped in nonmetal containers, in violation of its own requirements.

Our audit revealed that the agency needs to work toward a more cohesive formal process for managing GEO field releases.

Gaps in Field Test Requirements

We found that APHIS guidance for conducting field tests is neither consolidated nor comprehensive. APHIS regulations⁹ governing field releases do not include specific requirements to guide applicants during all phases of the process. To supplement the regulations, APHIS has issued guidance in various other forms, including Federal Register notices, memoranda, the APHIS website, and a manual for companies conducting

⁸ Selected from a universe of 1,020 field test sites, which we developed (see Scope and Methodology)

⁹ 7 CFR 340, dated January 1, 2002 and 2003



field tests. Yet, for some critical aspects of the field test process, APHIS has not established any specific requirements, either formal or informal.

For example, APHIS has not addressed the need for approved applicants conducting field tests to restrict public access to edible GE crops. Regulated GE crops are not distinguishable from traditional crops and have not been approved as safe to grow without regulation. In the absence of specific guidance, we found that one applicant planted regulated edible GE crops in an open field, where they were accessible to the public from a road and an adjacent nonregulated field.

Similarly, APHIS has not addressed the need for approved applicants conducting field tests to:

- provide the exact location of each planted field test site (see Finding 2);
- set a timeframe for disposing of harvests of high-risk GE crops at the end of the field test (see Finding 7); and
- promptly destroy GE crops at the conclusion of the field test so that their seeds do not spread outside the field test site (see Finding 8).

By closing these gaps in its existing guidance, APHIS can reduce the probability that GE crops will be inadvertently released into the environment, where some may persist unchecked.

Need for Greater Consistency in Communication and Implementation of Policy

We found that APHIS' public policy on the frequency of field test inspections differs from its actual practice. In the March 10, 2003, Federal Register, APHIS announced that it would "increase the number of inspections" during the 2003 growing season so that field test sites planted under pharmaceutical and industrial permits may be inspected seven times—up to five times during the growing season and twice during the postharvest period. In a press conference, an APHIS official demonstrated the agency's commitment to this goal by reiterating this policy for pharmaceutical crops: "Every test site will be inspected at least five times during the growing season and two times in the following season." However, for the 2003 growing season, APHIS did not conduct five inspections at each pharmaceutical and industrial field test site in our sample (see Finding 5).

APHIS has also understated to the public the percentage of inspected sites with compliance infractions. At the time of our audit work, APHIS reported on its website a 1.6 percent noncompliance rate for 7,402 authorizations of field tests. However, we found that "authorizations" represented the total number of approved permits and notifications, not all of which were planted, rather than the number of planted fields inspected by PPQ or reported to



APHIS by approved applicants. Since APHIS presents this noncompliance rate as evidence of its monitoring program's effectiveness, it is critical that APHIS report only the noncompliance rate on planted fields actually inspected by PPQ or reported by approved applicants.

In another inconsistency, we found that APHIS disregards its own regulations for shipments of GE seeds. Federal regulations require double metal containers for shipments of regulated GE material, regardless of whether the shipments are made under permits or notifications. According to the regulations, shippers can request a variance from the metal container requirement if they justify their request. On its website and in the user's manual for introductions, however, APHIS allows shippers to forgo using metal containers for regulated articles shipped under notifications. APHIS also allows permit holders to forgo using metal containers without obtaining formal variances. As a result, we found widespread use of nonmetal containers, such as bags and boxes, for shipping GE seeds. Metal containers were not used for any of the 199 interstate shipments in our sample (81 shipments under permits and 118 shipments under notifications). Only 6 of those shipments (2 shipments under a permit and 4 shipments under notifications) received variances from APHIS, leaving 193 shipments in violation of the regulations. To avoid inconsistent interpretation of its regulations, APHIS needs to clarify its regulations for shipments of GE seeds.

Enforcement Ability Limited by Incomplete Regulations

To make its requirements transparent to the public and enable it to take enforcement action when necessary, APHIS needs to assemble its various pieces of guidance in a comprehensive set of regulations. Especially in the sensitive area of GE crops, APHIS needs to ensure that its field release requirements are complete, consistent, subject to public scrutiny, and enforceable by regulation.

We noted that APHIS has not finished updating its regulations to comply with the Plant Protection Act of 2000, which was enacted on June 20, 2000. On July 16, 2001, APHIS partially updated its regulations to include the new authority of the Secretary of Agriculture to subpoena documentary evidence and witnesses to prosecute violators. APHIS still needs to update its regulations to reflect other provisions of the Act, which grant new regulatory authority to the Secretary of Agriculture for controlling noxious weeds. On January 23, 2004, APHIS began the process of updating its regulations by announcing in the Federal Register that it would prepare an environmental impact statement (EIS), in connection with potential changes to the regulations, regarding the movement and release of certain GEOs.



Internal Management Needs Improvement

Besides clarifying its regulations governing GE crops, APHIS needs to strengthen its internal processes for managing the field release program. Of greatest concern, APHIS' BRS has divided responsibility for monitoring field test sites between itself and PPQ; although BRS has overall control of the inspection program, it shares the authority to conduct inspections with PPQ. APHIS, however, has not clearly delineated the mutual responsibilities of BRS and PPQ in regard to inspections of GE field test sites. In the absence of an integrated, coordinated process between the two APHIS units, we found that PPQ was not performing the majority of inspections requested by BRS (see Finding 5). Although BRS and PPQ signed a MOU in September 2004, the MOU did not cover inspections of nonpharmaceutical and nonindustrial release permits, as well as movement permits. It also did not commit BRS to provide PPQ with planted notification sites to be inspected, nor did it require PPQ to perform all inspections requested by BRS.

Additionally, BRS and PPQ sometimes failed to follow their own internal procedures for reporting and enforcing noncompliance with regulations. We found that PPQ officers did not always prepare inspection reports or report violations found during our joint reviews. In addition, BRS received six reports of violations from PPQ officers, companies, and OIG. BRS also had other information in its files that it could have used to identify five additional violations. Thus, for 11 of the 15 violations identified during our audit, BRS had enough information to take administrative action, such as issuing a letter of warning. However, our review of BRS' compliance infraction database found that, as of December 17, 2003, none of the 11 violations was recorded. Although we found that BRS sent a guidance letter on 1 of the violations, it took no action on the other 10 violations (see Finding 5).

BRS advised us that, in 2004 and 2005, a new compliance branch subsequently began following up on compliance reports by auditing, reviewing, analyzing, and closing over 30 alleged violations.

APHIS also needs to further refine its procedures for selecting field test sites for inspection. At the time of our audit, the selection procedures were undocumented. APHIS advised us that, in April 2004, it began assigning risk scores to notifications, using a documented methodology, in order to direct PPQ inspections to higher risk GEOs. However, as before, the lists of notifications did not identify the exact locations of planted sites. Instead, the lists identified only the number of sites in each State. An APHIS official told us that APHIS plans to modify the risk scoring system as the agency gains experience with it.

Finally, we found that APHIS needs to document its procedures for approving applications—a function currently left to the judgment of



individual APHIS biotechnologists. To manage and track the volume of field test information it receives and reviews, APHIS also needs an effective, comprehensive management information system. At the time of our audit, APHIS lacked such a method of tracking field test data, including inspection reports and field test progress reports (see Findings 5 and 6). In 2005, APHIS implemented an interim inspection tracking system pending implementation of a comprehensive management information system.

We concluded that, to establish a cohesive oversight process for GE field releases, APHIS must continue to strengthen both its regulations and its internal management practices.

Recommendation 1

Revise and consolidate policies, procedures, and regulatory requirements for GE field releases.

Agency Response.

APHIS stated that this recommendation is consistent with the priorities set by BRS, including the revision of its regulations. APHIS stated that it will publish a draft programwide EIS in early 2006 and a proposed rule will follow. Rules are developed through public notice and comment, and therefore can take several years for completion. In addition, BRS has begun the consolidation and revision of guidance materials into a single *User's Guide* and expects to have a draft version completed in the spring of 2006.

OIG Position.

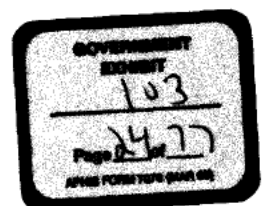
We agree with APHIS' planned corrective actions. To reach management decision, APHIS needs to provide estimated timeframes for implementation of the new regulations and the revised *User's Guide*.

Recommendation 2

Revise and clarify policies and regulations regarding the use of metal shipping containers.

Agency Response.

APHIS stated that it will clarify the shipping container requirements for permits and notifications in the revised regulations and *User's Guide*. BRS has begun the consolidation and revision of guidance materials into a single *User's Guide* and expects to have a draft version completed in the spring of 2006.



OIG Position.

We agree with APHIS' planned corrective actions. To reach management decision, APHIS needs to provide estimated timeframes for the implementation of the revised regulations and *User's Guide*.

Recommendation 3

Update regulations to incorporate the provisions of the Plant Protection Act of 2000.

Agency Response.

APHIS stated that it will publish a draft programwide Environmental Impact Statement (EIS) in early 2006. The EIS lays the foundation for a proposed rule to follow. The rule will include the provisions of the Plant Protection Act of 2000.

OIG Position.

We agree with APHIS' planned corrective action. To reach management decision, APHIS needs to provide an estimated timeframe for implementation of the new regulations.

Recommendation 4

Prioritize completion of the management information systems to track all information on permits and notifications.

Agency Response.

APHIS stated that BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, the Biotechnology Integrated Database System (BIDS), is fully developed and only awaits final review by the Office of the Chief Information Officer.

OIG Position.

We agree with APHIS' planned corrective action. To reach management decision, APHIS needs to provide the estimated timeframe for implementation of the ePermits tracking system and BIDS. Specifically, for the ePermits tracking system, APHIS needs to provide the estimated



completion dates for each phase of the ePermits tracking system: notification submissions, permit submissions, PPQ remote access to design protocols, and PPQ access to BRS imposed field test requirements.

Recommendation 5

Develop policy guidelines that address restricting public access to edible regulated GE crops, based on the risk of the type of crop, when conducting field tests.

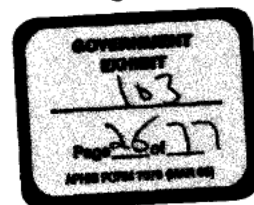
Agency Response.

APHIS disagrees with this recommendation. APHIS understands that the intent of this recommendation is to assure food safety. However, APHIS stated that the system of science-based risk assessment that is currently in place already addresses this issue. BRS can, for example, use permit conditions to require restricted access for any special cases where it might be deemed appropriate based on risk. The need for restricted access is most effectively addressed on a case-by-case basis where the biotechnologist can consider the type of trial, potential risks of the organism, and other information specific to the permit such as the exact site and locale.

FDA has supported the APHIS requirements and practices for edible regulated GE crops that have not undergone or completed FDA food safety review. FDA has authority over the safety of plant foods, including food from deregulated GE plants.

OIG Position.

We can not accept APHIS' management decision for this recommendation. To reach management decision, APHIS needs to provide its science-based risk assessment of regulated GE crops. APHIS also needs to provide FDA's food safety review and approval of APHIS requirements and practices for edible regulated GE crops.



Section 2. Application Process

Although APHIS is responsible for overseeing regulated GE crops and seeds, we found that, during the application process, the agency does not obtain certain critical information that it needs to carry out its oversight responsibility. Instead, APHIS relies on permit and notification holders to supply the necessary information at the time of field test inspections. Furthermore, we found that APHIS biotechnologists do not thoroughly document their scientific reviews of the information that applicants are required to submit.

Companies and organizations that wish to field test a regulated GEO must obtain APHIS approval by applying for either a permit or notification.

- The notification procedure is a simple, streamlined method of obtaining APHIS permission to introduce GEOs that APHIS considers relatively low-risk. To qualify, GEOs must meet specific eligibility criteria established by APHIS, and the applicant must agree to comply with performance standards designed to ensure biological confinement of the GE crop.¹⁰
- GE crops that do not qualify for the notification process require permits, which are used for experimental plants that APHIS considers higher risk, such as plants that produce pharmaceutical and industrial compounds. Permit applications require more detailed information about the field test, and APHIS evaluates them more closely than applications for notifications.

We found that APHIS is not aware of the locations of all planted GE field test sites, weakening its oversight of the field release program. APHIS does not always require permit and notification applicants to identify the precise location of field sites where they plan to plant experimental GE crops, nor does it follow up with approved applicants to obtain this information once the crops are in the ground. In fact, APHIS may know only the business address or State and county where the field is planted. We also found that, even though the vast majority of field tests are conducted under notifications, notification applicants are not required to submit their written protocols, which describe how the applicant plans to contain the GE crop within the field test site. Instead, APHIS allowed applicants to verbally discuss their written protocols at the time APHIS conducted its field test inspections. On May 2, 2005, APHIS revised its approval letter for notifications to require written protocols at the time of inspection.

¹⁰ Performance standards are detailed in 7 CFR 340.3©, dated January 1, 2003.



Given the increasing numbers of field test applications each year—from 9 requested applications in 1987 to over 950 in 2004—APHIS must take action to strengthen its controls over the application process.

Finding 2

Locations of Planted GE Field Test Sites Are Not Always Known

APHIS cannot fulfill its responsibility to oversee GE field tests without knowing the exact locations of planted field test sites. We found that APHIS does not consistently collect precise location information during the field test process, either at the time of application or while the field test is underway. For our sample of 91 field tests,¹¹ the applications did not disclose the exact locations. In fact, we found that four companies that held either a permit or notification did not have location information readily available for some of their planted field test sites. APHIS' lack of a master list identifying where GE crops are planted impairs its ability to monitor compliance with field test requirements.

Precise Locations Not Included in Application

APHIS regulations in effect during 2002 and 2003 state that applicants requesting approval to field test a regulated article under the notification process must provide the field site location for the release.¹² Applicants requesting a permit are required to provide a detailed description of the field trial location of the regulated article.¹³ Despite the regulations, APHIS officials told us that applicants cannot determine the exact site locations with any accuracy prior to planting. Because the regulations do not specify the kind of location information applicants must submit, APHIS receives a variety of location descriptions, many of which are not sufficient to locate the field test site. Of the 23 permit applications¹⁴ we reviewed, 85 percent indicated the company's business address as the planting location. Of the 28 notification applications¹⁵ we reviewed, none specifically identified field site locations.

On January 14, 2004, APHIS issued a letter to pharmaceutical and industrial permit applicants that provided new and updated instructions for submitting a permit application. Specifically, the letter required submission of GPS coordinates for all field test sites, after planting, to establish the boundaries of the site. However, the new requirement for GPS coordinates does not extend

¹¹ Selected from an universe of 1,020 field test sites, which we developed (see Scope and Methodology).

¹² 7 CFR 340.3(d)(2)(iii), dated January 1, 2002 and 2003

¹³ 7 CFR 340.4(b)(11), dated January 1, 2002 and 2003

¹⁴ Selected from a universe of 32 permits, which we developed (see Scope and Methodology)

¹⁵ Selected from a universe of 228 notifications, which we developed (see Scope and Methodology)



to notifications or permits other than pharmaceutical and industrial.¹⁶ On January 24, 2005, APHIS issued a memorandum that requested, but did not require, notification holders to submit GPS coordinates or other information to identify the site after planting, effective April 5, 2005. A BRS official advised us that the notification holders currently provide this information voluntarily, because the regulations do not require them to submit it.

Supplementary Reports Inconsistent on Location

Because any location information included in the application is submitted before planting takes place, APHIS needs additional information to locate the field test sites that have actually been planted. Based on the biotechnologist's review of the permit application and experience with the applicant, APHIS can require permit applicants to provide supplementary reports. However, we found that, like the field test applications, these supplementary reports do not always require specific location information that would allow APHIS to easily locate the field test sites. Furthermore, APHIS does not uniformly require these reports for all permits, and they are not required at all for notifications.

Two of the supplementary reports that APHIS requires from some approved permit applicants are planting notices and 4-week/28-day reports. The planting notice indicates when a crop is about to be planted, and the 4-week/28-day report provides more detailed information on the field location once the field test is underway. Our review of 53 permit field sites included 20 field sites planted under 13 pharmaceutical and industrial permits. All 13 permit holders were required to submit planting notices and 12 were required to submit 4-week/28-day reports. However, only 8 of those 12 permit holders were required to provide GPS coordinates on their 4-week/28-day reports; three failed to provide this information. Although not required to do so by APHIS, one permit holder indicated the specific field site location on the planting notice.

In addition to planting notices and 4-week/28-day reports, APHIS may also require permit holders to submit harvest/termination notices, which inform APHIS of the anticipated harvest date for the GE crop. APHIS also requests, but does not require, that approved notification applicants provide 5 days' notice if they decide not to proceed with field testing at an approved location; approved permit applicants are not required to notify APHIS if they decide not to plant at a proposed field test location. Because it does not always require harvest/termination notices and decisions not to plant from all permit and notification holders, APHIS was not aware that 30 of the approved field test sites in our sample had not been planted or that 8 sites had been harvested. Without knowing which proposed field test locations have not

¹⁶ The letter also applies to bioremediation permits, which were not covered in this audit. Bioremediation is the use of biological agents, such as bacteria or plants, to remove or neutralize contaminants, as in polluted soil or water.



been planted or have been removed from the ground, APHIS cannot effectively monitor compliance with field test requirements through onsite inspections.

Inspections Hindered by Missing Information

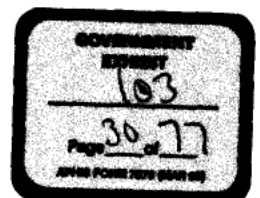
Lacking a master list of planted field test sites, APHIS must rely on approved applicants or their representatives (cooperators, farmers, planters, or researchers) to provide the exact location of GE crops before a site inspection can be performed. This is not an effective control, especially given that some of the permit and notification holders do not have exact location information readily available. Of the 12 companies we contacted for this information, 4 were not able to provide locations for some of their planted GE test sites, even 1 to 2 weeks after our request. One company representative said the company's information could contain errors or omissions due to the short timeframe, and three others said their lists of planted sites were incomplete. In fact, although 1 representative was able to provide locations for about 350 of the company's field tests, the representative wrote that the company did not have planting and location information on about 1,000 additional field tests. Another representative said that it would take from 1 to 3 months to gather the location information.

Additionally, because APHIS does not require all approved applicants to notify the agency when they terminate a field test or decide not to plant, it cannot supply PPQ with a valid list of planted sites to inspect. For example, according to a PPQ regional program manager, an average of 20 percent of the inspection requests his office received from BRS in 2003 and 2004 were for field test sites that had not been planted. Thus, APHIS dedicated valuable resources to compiling inaccurate inspection lists and contacting applicants who had not planted regulated GE crops.

Database Inadequate to Track Vital Information

To track field test information, APHIS uses a computerized database that was implemented in 1992. Our review of the database found that it does not have data fields to record proposed and planted field test site locations and to track significant events at field test sites. Significant events include planting, harvesting, cancellation, or termination of the field test. The database also does not alert APHIS when requested information is late or has not been received from approved applicants (see Finding 6). According to an APHIS official, the agency is currently working to design a new system that will track all necessary field test information with potential implementation in September 2005.

We concluded that, in order to maintain accountability for regulated GE crops, APHIS needs to know precisely where those crops are planted. An APHIS official told us that identifying the precise location of a field test site



at the time of application is an unrealistic requirement, because applicants cannot determine the exact site locations with any accuracy prior to planting. However, on January 24, 2005, APHIS issued a memorandum that requested notification holders to submit GPS coordinates or other information to identify the site after planting, effective April 5, 2005. Specifically, the memorandum requested, but did not require, the State, county, internal identification number (if available), central GPS coordinate, or address. The memorandum also requested that notification holders advise APHIS of sites listed in the notification that they do not intend to plant.

Although APHIS officials told us that voluntary compliance by major notification holders has been high, APHIS needs to strengthen its reporting requirements for field tests so that inspections can be made at critical stages of the process for permits and at least once for a sample of notifications.

Recommendation 6

Revise regulations to require all permit and notification holders to submit planting notices, 4-week/28-day reports, and harvest/termination reports for all field test sites.

Agency Response.

APHIS agrees in part with this recommendation but disagrees with the requirement for planting notices for the notifications because these notices are necessary only in cases where a preplant inspection is warranted. With the completion of the new regulations, BRS will require the 4-week/28-day reports for all field tests. Thus, BRS will know what has been planted within 28 days for all field tests. BRS has already strengthened reporting guidelines for notifications in the 2005 growing season and is currently evaluating the various field report requirements for permits and notifications with the conclusions to be reflected in the new regulations. BRS already requires reports six months after harvest/termination.

OIG Position.

We can not accept APHIS' management decision for this recommendation for three reasons.

- BRS is currently evaluating the various field report requirements for permits and notifications. As a result, the corrective action plan is contingent on the results of the evaluation.
- BRS did not propose interim measures that require notification and permit holders to submit 4-week/28 day reports pending release of the new regulations.



- The 6-month field test report is not adequate for a timely harvest/termination notice, because the 6-month field test report is due half a year after the harvest or termination of the field test.

To reach management decision, APHIS needs to provide a corrective action plan based on its evaluation of field reporting requirements. APHIS also needs to implement interim measures until its regulations are revised.

Recommendation 7

Revise regulations to require all permit and notification holders to submit the GPS coordinates of field test sites on all reports submitted after planting.

Agency Response.

APHIS stated that this recommendation is consistent with the direction set by BRS and, in fact, BRS has already requested that GPS coordinates of each field site be submitted in 28-day planting reports. Additionally, BRS is incorporating field test location information requirements into its regulatory revisions.

OIG Position.

We agree with APHIS' planned corrective action. To reach management decision, APHIS needs to provide an estimated timeframe for implementing the new regulations.

Recommendation 8

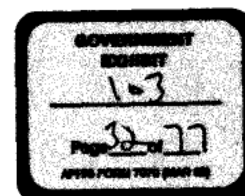
Revise regulations to require all permit and notification holders to submit notices of decision not to plant if they decide to cancel an approved field test location.

Agency Response.

APHIS has made revision of its regulations a priority, and this issue will be addressed as part of that process. Currently, this information is already requested of all growers through our guidelines.

OIG Position.

We agree with APHIS' planned corrective action. To reach management decision, APHIS needs to provide an estimated implementation date for the revised regulations.



Recommendation 9

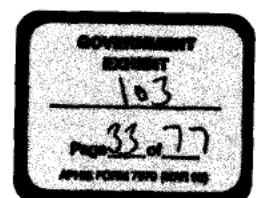
Complete work on the management information system and ensure that it is capable of recording necessary information related to field test sites, including the specific location of each field site and the dates of significant events.

Agency Response.

APHIS referenced its response to Recommendation 4. It stated that a new database system is already designed to capture all of the OIG-recommended information and more. BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, BIDS, is fully developed and only awaits final review by the Office of the Chief Information Officer.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide timeframes for implementation of the referenced information systems.



Finding 3**Written Field Test Protocols Are Not Always Obtained From Applicants**

Most field tests of regulated GE crops are conducted under notifications. APHIS, however, does not require notification applications to include written protocols, which describe the procedures applicants will use to meet the field test performance standards prescribed by regulation.¹⁷ Consequently, protocols do not undergo scientific review by an APHIS biotechnologist prior to approval of the notification application. Instead, because the procedures for crops planted under notification are well known, APHIS allows approved applicants to provide verbal protocols at the time of inspection. This practice impacts the integrity of both the approval and inspection processes.

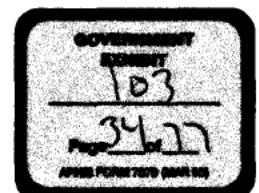
Field test protocols detail how applicants will meet the critical performance standards for introductions of GE crops, including devitalization, monitoring for volunteer plants, and preventing inadvertent mixing of regulated GE articles with nonregulated articles. APHIS regulations do not require notification applicants to submit a written copy of their protocols with the application. Rather, the regulations state only that APHIS may issue guidelines regarding scientific procedures, practices, or protocols that it has found acceptable. A person who wishes to field test a GE crop may follow APHIS' protocol guidelines or adopt different protocols. When an applicant chooses to follow different protocols, the applicant may, but is not required to, discuss the matter in advance with APHIS to ensure that the protocols will be acceptable to APHIS.¹⁸

No Scientific Review of Notification Protocols

Because notification applicants are not required to submit their protocols with the application, APHIS biotechnologists do not review notification protocols for adequacy prior to granting the notification. An APHIS study issued in 2001 shows that such a preliminary review is necessary. The study, which covered mid-1997 to 2000, concluded that some notification protocols might not be adequate to meet the field test performance standards and identified several major areas in need of improvement. In a letter to its customers dated March 19, 2001, APHIS addressed those issues by providing guidance on some plant species' persistence in the environment, methods to minimize pollen movement, and elimination of volunteers. However, APHIS did not implement management controls requiring notification applicants to submit written protocols with their applications for scientific review, a requirement

¹⁷ 7 CFR 340.3©, dated January 1, 2003

¹⁸ 7 CFR 340.3, dated January 1, 2003, footnote 5



that would have enabled APHIS to determine whether performance standards would be met.

In contrast to the notification application process, APHIS requires permit applicants to submit a detailed description of the proposed procedures, processes, and safeguards that will be used to prevent the dissemination of regulated GEOs at each planned field test site.¹⁹ These higher risk permit protocols undergo a biotechnologist review for adequacy before the permit is approved. Until APHIS extends this review to notifications, some notification protocols may not be adequate, increasing the risk of inadvertent release of GEOs into the environment.

Contradictory APHIS Guidance

Once it approves the notification application, APHIS does not require notification holders to provide written protocols during the field test. Our review of 90²⁰ notification approval letters found that APHIS allowed all notification holders to provide verbal protocols to the PPQ inspector; APHIS regulations²¹ do not specify that the protocols must be in writing. However, APHIS' inspection manual²² contradicts the approval letters and the regulations by directing PPQ inspectors to determine if notification holders have written protocols and if they are following the protocols.²³ The manual also states that if the notification holder or cooperator does not have a copy of the site-specific protocols at the time of inspection, it is a violation of the notification. This lack of uniform APHIS guidance undermines the inspection process.

As part of our review, we conducted joint inspections with PPQ officers at 87²⁴ of the 91 field sites in our sample. When we asked one company for copies of the protocols for nine of its notification sites, a company representative advised us that APHIS regulations²⁵ did not require written protocols. Instead, the company's field personnel provided a verbal description of the protocols. Without a copy of the company's written protocols that had been approved by APHIS, the inspectors could not be certain which protocols the notification holder was following and whether those protocols met the performance standards. After we completed our field visits, the company provided the written protocols to us; however, it was too late for us to determine whether the protocols were followed in the field.

On May 2, 2005, APHIS revised its approval letter for notifications to require written protocols at the time of inspection. However, in contradiction, the

¹⁹ 7 CFR 340.4(12), dated January 1, 2003

²⁰ This included 28 approval letters from our original sample and 64 added during fieldwork.

²¹ 7 CFR 340.3, dated January 1, 2003, footnote 5

²² Biotechnology Inspection Manual for Notification Field Release, page 3.21, March 2002

²³ Biotechnology Inspection Manual for Notification Field Release, page 3.19, March 2002

²⁴ PPQ officers were not available to accompany us on the inspections of four field sites.

²⁵ 7 CFR 340.3, dated January 1, 2003, footnote 5



revised inspection manual distributed to PPQ officers in February 2005 states that notification protocols do not have to be in writing. To ensure that field test procedures are effective, we concluded that APHIS should require notification applicants to submit protocols in writing at the time of application, review them for adequacy, and ensure that PPQ officers have access to the protocols before they inspect the field site.

Recommendation 10

Amend regulations to require applicants for notifications to submit written protocols prior to approval of the field test.

Agency Response.

APHIS disagrees with this recommendation. While APHIS does evaluate written protocols for permits, it believes that the current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. Based on APHIS' familiarity with the crops eligible for notification, it does not feel it is warranted to require or review written protocols prior to approval of field tests. Performance-based regulatory standards are commonly used in APHIS and other regulatory agencies, and APHIS' use of this approach for notifications has been acknowledged as appropriate by the National Academy of Sciences. The intent of the notification procedure is to provide an administratively streamlined process for trials of crop-trait combinations with which APHIS already has a great deal of experience and familiarity.

OIG Position.

We can not accept APHIS' management decision for this recommendation. Performance-based regulatory standards do not preclude submission of protocols to APHIS prior to approval of the field test. Performance-based regulatory standards set objectives and desired outcomes without specifying how they are to be achieved, thus giving approved applicants the flexibility to determine how these objectives/outcomes can be met. APHIS is relinquishing its regulatory responsibility in favor of self-certification by the notification applicants—namely the applicants merely certify in their notification applications that they will meet the performance standards. Yet, in 2001, APHIS' own survey of notification protocols found that some protocols may not be adequate to meet the field test performance standards. Without documented approved protocols, APHIS has no basis to determine if the applicant's procedures meet the performance standards. To reach management decision, APHIS needs to provide its science-based support for its policy that written protocols will not be required or reviewed prior to approval of field tests.



Recommendation 11

Require and document biotechnologist reviews of notification protocols to ensure they are sufficient to meet performance standards.

Agency Response.

APHIS disagrees with this recommendation, referring to its response to Recommendation 10. While APHIS does evaluate written protocols for permits, it believes that the current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. Based on APHIS' familiarity with the crops eligible for notification, it does not feel it is warranted to require or review written protocols prior to approval of field tests. Performance-based regulatory standards are commonly used in APHIS and other regulatory agencies, and APHIS' use of this approach for notifications has been acknowledged as appropriate by the National Academy of Sciences. The intent of the notification procedure is to provide an administratively streamlined process for trials of crop-trait combinations with which APHIS already has a great deal of experience and familiarity.

OIG Position.

We can not accept APHIS' management decision for this recommendation. Performance-based regulatory standards do not preclude biotechnologist reviews of notification protocols to ensure they are sufficient to meet performance standards. To reach a management decision, APHIS needs to propose an appropriate management control to ensure that protocols meet performance standards.

Recommendation 12

Distribute written protocols to PPQ officers to use in conducting inspections of field test sites planted under notifications.

Agency Response.

APHIS stated that PPQ officers currently have access to written protocols at the field test site. In addition, field test design protocols for notifications will be included in APHIS' database system (see response to Recommendation 4), which can be accessed by PPQ inspectors prior to their inspections.

OIG Position.

We can not accept APHIS' management decision for this recommendation. Like the approved notifications, the protocols are important control documents that the PPQ officers should receive from APHIS before the inspection. The field design protocols, mentioned in APHIS' response, are



only examples of possible protocols for certain crops. Since notification holders are not required to follow these examples, deviations from the examples are not violations. To reach management decision, APHIS must obtain and distribute written protocols to PPQ officers as a part of the applications it already distributes to PPQ.

Finding 4

Scientific Reviews of Field Test Applications Are Not Sufficiently Documented

In our review of the official files for 10 pharmaceutical permits, we found little documentary evidence of the scientific reviews performed by APHIS biotechnologists. We attributed this to the fact that APHIS biotechnologists do not follow a standardized process to document scientific reviews of permit applications. APHIS also has not issued policies and procedures requiring supervisory reviews of the biotechnologists' work. Although the biotechnologists' current application reviews may be adequate, documented, standardized processes and supervisory review help ensure that the scientific reviews are consistent and sufficient for approving the introduction of regulated GE crops, including pharmaceuticals and industrials.

OIG is not equipped to evaluate the scientific adequacy of individual biotechnologist's reviews, and we did not attempt to do so. However, we examined the official files to determine what documentation was maintained to support the scientific review. The Government Accountability Office's Standards for Internal Control in the Federal Government²⁶ states that internal controls need to be clearly documented and the documentation should be readily available for examination. Review is one kind of internal control.

APHIS has not described the biotechnologist review process in detail in the APHIS BRS Permit Functions Quality Manual,²⁷ which documents procedures for processing applications. For permits, APHIS staff explained that documentation of scientific review is to include the biotechnologist's initials on a tracking sheet; a completed form identifying the plant's genes and other characteristics; their initials or signature on a letter reporting the results of the review to the State regulatory personnel where planting was proposed; and their initials on the APHIS approval letter. Additionally, in 2003, APHIS issued two draft checklists for limited reviews of pharmaceutical and industrial permit applications. The checklists are specific to reviewing and approving applicants' protocols for cleaning equipment and storage facilities, and for reviewing and approving the applicants' employee training programs.

²⁶ GAO/AIMD-00-21.3.1, dated November 1999

²⁷ January 31, 2003



During our fieldwork, we obtained copies of the official files for 10 pharmaceutical permits,²⁸ which APHIS considers high-risk. Our review found that the files did not contain sufficient information to disclose the extent of the biotechnologist's reviews or the criteria they used to arrive at their decisions. Although the files contained letters to State regulatory personnel, we found that other required documentation was not always in the files. For all 10 of the permits, the tracking sheet was not in the file or not initialed. For 7 of 10 permits, the form to identify the plant's genes and other characteristics was also not in the file or not completed. Furthermore, nine of the approved permits had not undergone supervisory review, an essential control over the application approval process.

Even if the required documentation had been present in the files, we concluded that it would not be sufficient to describe the biotechnologists' complete review process. Specifically, the documentation was not sufficient because it did not describe the scope of the biotechnologists' review of risks associated with introducing a particular GE plant and how the applicant planned to mediate those risks. Scientific criteria for approving a field test application might address the likelihood of the unintentional spread of GEOs or the establishment of wild GEO populations, and the effects of regulated GE crops on other species.

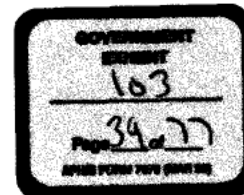
Recommendation 13

Develop and implement policies and procedures for documenting the scientific process and criteria for approving applications, and require supervisory reviews of biotechnologists' work.

Agency Response.

APHIS stated that BRS has developed and implemented six new standard operating procedures related to the scientific review process. BRS is currently formulating plans for increased documentation and supervisory review of the process. Many of these plans will be implemented before the end of fiscal year 2006. However, BRS believes major actions to address this recommendation will continue to be ongoing to ensure that a continual process of updating and improvement is in place. Further, the consolidated *User's Guide* under development will articulate our review process and approval criteria.

²⁸ Judgmental sample of 10 pharmaceutical permits planted in 2002



OIG Position.

We agree with planned corrective actions. To reach management decision, APHIS needs to provide timeframes for implementation of the corrective action described.



Section 3. Management and Oversight of Field Tests

Permit and notification holders must ensure that planted GE crops do not persist in the environment outside the field test site. Once the field test ends, GE crops must be properly destroyed or disposed of, and the field test site must be monitored for volunteer plants or regrowth of the crop in the following season. At these critical stages of the field test process, effective management and oversight are essential to reduce the risk of inadvertent persistence of regulated GE crops in the environment. We found several weaknesses in APHIS' controls over field tests—specifically, inspections, reporting from permit and notification holders, and postharvest guidance.

Management of Inspections Needs Improvement

Two APHIS units, BRS and PPQ, share responsibility for inspections of GE field test sites. BRS manages the overall inspection process, but it relies on PPQ to perform the majority of the inspections; BRS performs few inspections itself. However, at the time of our audit, the two units had not clearly delineated how they would coordinate their inspection-related activities. We found that PPQ did not conduct all inspections of high-risk pharmaceutical crops that were requested by BRS. Also, BRS did not establish objectives for inspecting a specific number of notification field test sites. Therefore, many inspections requested by BRS were not conducted by PPQ. We found that this was because PPQ did not know what APHIS' inspection expectations were for either pharmaceutical/industrial permits or other permits/notifications.

In September 2004, BRS and PPQ entered into a MOU to clarify the relationship between BRS and PPQ regarding the inspection program for field test sites. However, we found that the MOU did not cover inspections of nonpharmaceutical and nonindustrial release permits, and movement permits. It also did not commit BRS to provide PPQ with planted notification sites to be inspected, nor did it require PPQ to perform all the inspections requested by BRS.

During most of our audit, BRS also did not have an effective means of tracking inspection requests and results. As a result, it was not aware of which sites had been inspected or the total number of inspections performed. At the end of our audit, in 2005, BRS advised that it had implemented an interim system for tracking inspections, while a new system is being developed.



Reporting Problems Not Addressed

APHIS requires various reports from permit and notification holders at different points in the life cycle of the GE crop, from advance notice of planting to the final field test results required from all approved applicants. We found that permit and notification holders often submitted the required reports late or not at all. Because it does not have an effective system for tracking receipt of field test progress reports, APHIS does not always follow up on late and missing reports or assess penalties for noncompliance.

Postharvest Guidance Incomplete

At the conclusion of the field test, APHIS requests that permit and notification holders properly dispose of all GE plant material and monitor their field test sites to ensure that volunteer plants do not persist in the environment during the following growing season. However, we found that APHIS has not established timeframes for promptly devitalizing crops at the conclusion of the field test. APHIS also does not require permit holders to notify it of the final disposition date of high-risk GE harvests.

Although APHIS has taken positive steps toward remedying inspection problems during our audit, it needs to continue strengthening its field test inspections, reporting process, and postharvest guidance in order to carry out one of the goals of its strategic mission: ensuring the safe release of agricultural biotechnology.

Finding 5

APHIS Needs to Establish an Effective Inspection Program to Monitor Regulated GE Crops

APHIS was not using its inspection authority effectively to monitor field tests of GE crops. We found that, until 2004, APHIS lacked a formal risk-based process for selecting field test sites for inspection and that the majority of assigned inspections were not completed. Specifically, APHIS announced to the public that pharmaceutical and industrial field sites would be inspected 5 times during the 2003 growing season, but, in fact, we found that only 1 of 12 sampled pharmaceutical field test sites met this requirement. Additionally, 46 percent of the notifications²⁹ APHIS selected for inspection were not inspected. We also noted that inspectors did not always report violations at field test sites, and APHIS did not follow up on all violations that were reported. These problems stemmed from APHIS' lack of clear, complete inspection requirements, as well as a lack of coordination between BRS and PPQ, the APHIS units that share responsibility for monitoring GE field test

²⁹ Field test sites with releases ending during or after June 2002, the month in which BRS' responsibilities for biotechnology began.



sites. As a result, APHIS had little assurance that field tests are being conducted safely, in a way that minimizes the potential for GE plants to persist in the environment.

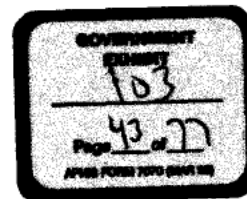
APHIS regulations, dated January 1, 2003,³⁰ do not specify the number of inspections required at GE field test sites or how field test sites should be selected for inspection. Instead, BRS and PPQ followed an informal process to carry out inspections of GE field test sites. Although BRS had no documented process for selecting field test sites before 2004, a BRS official told us that BRS forwarded all permits and a sample of 10 to 12 percent of approved notifications to 2 PPQ regional managers for inspection. The PPQ regional managers then distributed the requests for inspections to the appropriate APHIS State plant health director for assignment to PPQ officers.

Although APHIS had not issued inspection requirements directly to BRS and PPQ, APHIS announced in the Federal Register on March 10, 2003, that all field test sites planted under pharmaceutical and industrial permits may be inspected seven times—up to five times during the growing season and twice during the postharvest period. In a March 6, 2003, press conference, making a public commitment to this goal, an APHIS official assured the public that all pharmaceutical and industrial sites would be inspected five times during the growing season and two times during the postharvest period. For all other permits and selected notifications, an APHIS official told us that PPQ attempted to inspect at least one field test site planted under each permit or notification. However, at the time of our audit, we found that PPQ did not know what APHIS' inspection expectations were for either pharmaceutical/industrial permits or other permits/notifications.

Requested and Required Inspections Not Performed

PPQ did not inspect all pharmaceutical and industrial field test sites planted in 2003 five times during the growing season, contrary to the inspection guidelines APHIS announced to the public and published in the March 2003 Federal Register. In fact, only 1 of our sample of 12 pharmaceutical and industrial sites planted in 2003 had all 5 required inspections. Only 18 of the 55 (11 x 5) potential inspections were performed for the remaining 11 sites in 2003. According to the Federal Register notice and APHIS management, PPQ also should have inspected pharmaceutical and industrial fields planted in 2002 twice during their postharvest period in 2003. We found that only 7 of the 14 (7 sites x 2) potential inspections were performed for our sample of 7 pharmaceutical sites planted in 2002. Because PPQ did not conduct all postharvest inspections, the following potential violation at a high-risk pharmaceutical field test site went undetected:

³⁰ 7 CFR 340, dated January 1, 2003



- In September 2003, we visited a field test site where a permit holder had planted a pharmaceutical crop in 2002. PPQ had not inspected the site during the postharvest monitoring period in 2003. When we visited the site, we learned that the permit holder's cooperator had planted soybeans on the field, violating APHIS requirements that restrict the production of food and feed crops at pharmaceutical and industrial GE field test sites in the following season.³¹ Those GE field test sites are to be left fallow in the following growing season so that volunteer GE plants are not inadvertently harvested with an unregulated food crop. Although the cooperator's 2003 monitoring record stated that the 2002 GE field was fallow, the cooperator told us that he had planted unregulated soybeans in the former GE field and cut them down the day before our visit. He left the soybeans standing in the larger field surrounding the former GE field.

We also found a similar incident at a field test site that PPQ inspected only once during the 2003 postharvest monitoring period. The cooperator planted unregulated soybeans in 2003 on the same acreage where a pharmaceutical crop was planted during the 2002 growing season. However, the PPQ officer did not report this as a violation to BRS (see "Inspection Results Not Reported or Tracked"³² below).

According to BRS records, a total of 906 notifications were referred to PPQ for inspection. Our review found that PPQ conducted only 485 inspections, or approximately 54 percent of those requested. Thus, for 46 percent of the notifications that should have been inspected, APHIS had no assurance that field tests were conducted in accordance with regulations.

Neither BRS nor PPQ was aware of the number of inspections completed. Despite previous OIG audit recommendations to develop an inspection tracking system,³³ BRS lacked an adequate method of accounting for all inspections and their outcomes, including inspections of high-risk pharmaceutical fields. Although PPQ's Western region used a database to track some inspections, PPQ's Eastern region did not have a similar tracking system. The Eastern region's PPQ manager stated that, if BRS requested a field test inspection for a specific permit and BRS did not receive the inspection report, it was BRS' responsibility to follow up and ensure the inspection was completed. BRS, however, did not have a followup process to determine if requested inspections were completed.

At the end of our audit, in 2005, BRS advised that it had implemented an interim system and procedures for initiating, numbering, tracking, and receiving written followup on every inspection. It is using the interim system

³¹ Federal Register, section II.1.B, March 10, 2003

³² Field test sites with releases ending during or after June 2002, the month in which BRS' responsibilities for biotechnology began.

³³ In Audit Report 33099-9-Hy, dated August 1994, OIG recommended that APHIS' Biotechnology, Biologics and Environmental Protection, a predecessor of BRS, work with PPQ to develop procedures to account for and verify all PPQ inspection reports, noting violations or potential violations.



while a new system is being developed. The effectiveness of the interim system has not been reviewed or tested by OIG.

Selection Process Not Documented or Site-Specific

Prior to April 2004, APHIS' process of selecting notifications from the BRS database and forwarding them to PPQ for inspections was undefined and ambiguous. We found that BRS had not documented how it selected its sample of 10 to 12 percent of notifications for inspection. According to an APHIS official, the notification sample was selected based on risk factors—such as crops with new gene variations, applicants who had not conducted field tests before, and applicants with previous violations. However, we found no documentation of the risk factors used to select notifications for inspection.

APHIS advised us that, in April 2004, it began using a documented methodology to assign risk scores to notifications and direct PPQ inspections to higher risk GEOs. An APHIS official also told us that APHIS plans to modify the risk scoring system as the agency gains experience with it. However, as before, rather than selecting specific field test sites for inspection, BRS forwards entire permits and notifications to PPQ, even though each permit or notification may cover numerous field test sites. PPQ then decides which field test site to inspect under a given permit or notification, sometimes based on how convenient the site is for the inspector to visit. APHIS should select specific field test sites for inspection according to their risk level. As discussed in Finding 2, however, APHIS could not select specific sites for inspection because APHIS did not always know if, and where, approved field test sites were planted. Consequently, APHIS had no assurance that the highest risk field test sites were being selected for inspection.

Inspection Results Not Reported or Tracked

BRS and PPQ sometimes failed to follow their own internal procedures for reporting noncompliance with regulations. PPQ officers did not always prepare inspection reports and did not always report violations of regulations³⁴ found during our joint review. During our joint inspections with PPQ officers, we found a pharmaceutical site that was not left fallow and two cases where monitoring records for pharmaceutical crops were not maintained by the cooperators. We also identified one applicant who had exceeded the approved acreage to plant under notification. The PPQ officers did not report these violations to BRS.

We also found that BRS failed to take action on 11 violations—6 violations reported to BRS by PPQ officers, approved applicants, and OIG and 5 other

³⁴ 7 CFR 340.3 and 340.4, dated January 2003



violations that BRS could have identified from information it already had. The six reported violations included a lack of dedicated storage facilities for farm equipment, failure to retain border rows, shipment of a regulated article after the notification expired, two instances of planting with no permit, and one instance of planting in an unapproved location. Regarding the five identifiable violations, BRS failed to compare the permit requirements with the field test progress report, which would have identified two violations of shipping requirements and two violations for planting regulated articles in unapproved locations. BRS also failed to identify another pharmaceutical site that was not left fallow, even though the PPQ officer's report, while not reporting a violation, mentioned the current crop growing at the site.

Our review of BRS' compliance infraction database found that, as of December 17, 2003, none of the 11 reported or identifiable violations was recorded, and BRS took action on only 1 of the 11 violations. The BRS official maintaining the database could not explain why the compliance infractions were not recorded in the database. The failure to report inspection results and follow up on violations increases the risk of an unauthorized release of regulated GEOs into the environment.

In 2004 and 2005, a new compliance branch began following up on all compliance reports by auditing, reviewing, analyzing, and closing over 30 alleged violations, but took no action on the remaining 10 violations.

By finalizing its inspection tracking system, further defining the relationship between BRS and PPQ, and refining its inspection requirements and selection procedures, APHIS can significantly strengthen the inspection process and its oversight of regulated GE plants.

Recommendation 14

Establish requirements for the number of field-site inspections to be performed for permits and notifications.

Agency Response.

APHIS stated that BRS has always had requirements for field-site inspections. The Compliance and Enforcement Branch has implemented documentation procedures for field-site inspections and strengthened and clarified the requirements for the selection of field sites. APHIS is continuing to strengthen its inspection requirements by developing new procedures for selection of field-site inspections based upon key risk-related factors, and is always updating and improving its procedures based upon experience and new knowledge about risk-related factors. APHIS is also considering additional inspection requirements as it develops its new regulations.



OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide additional information on how APHIS will establish requirements for the selection of specific field sites and the number of sites to be inspected and the timeframes for implementation of the corrective actions described.

Recommendation 15

Develop and implement written policies and procedures for selecting specific field test sites for inspection based on risk.

Agency Response.

APHIS disagrees with this recommendation, stating that individual field-trial sites within a given notification or permit are of comparable risk. Once a notification or permit has been selected for inspection by BRS' risk assessment, allowing PPQ inspectors the flexibility to choose the specific inspection site within the permit or notification encourages more efficient use of Government resources without compromising safety.

OIG Position.

We can not accept APHIS' management decision for this recommendation. The National Academy of Sciences states that "risks must be assessed according to the organism, trait, and environment."³⁵ Thus, the environment—i.e., the field site location—is an important risk factor that should be considered in selecting field test sites for inspection. To reach management decision, BRS needs to issue criteria for assessing environmental risks as guidance for selecting fields for inspection.

Recommendation 16

Clarify the specific roles and responsibilities of BRS and PPQ in the MOU regarding the selection and inspection of nonpharmaceutical and nonindustrial release permits, and movement permits.

Agency Response.

APHIS stated that BRS and PPQ have already established an MOU that addressed BRS' inspection requirements for each type of permit, including nonpharmaceutical and nonindustrial permits, as well as the notifications. The MOU was originally written in a manner so that responsibilities were clear to both BRS and PPQ and was implemented without any problems.

³⁵ National Academy of Sciences, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, page 63, finding 2-4



However, OIG interpreted the language in the MOU differently and suggested that problems could arise. BRS and PPQ have made revisions to the MOU to address this concern.

OIG Position.

To reach management decision, APHIS needs to provide the details of changes made to the MOU and the date the process was implemented.

Recommendation 17

Finalize the inspection tracking system and ensure that it is effective in recording the receipt of inspection reports, inspection results, and the number of inspections completed.

Agency Response.

APHIS stated that this recommendation is consistent with the priorities already set by BRS. BRS currently has a system in place to track all of the recommended data and an improved database system for tracking inspection and field data reports has now been fully developed and will be operational after a final review by the Office of the Chief Information Officer (see response to Recommendation 4).

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide timeframes for implementation of the corrective actions described.

Recommendation 18

Finalize and implement management controls to require reporting of all inspections to BRS for review and followup on violations of regulations.

Agency Response.

APHIS stated that the problems cited by OIG are currently addressed by an interim system already in place. Now that these management controls are operational, they will be consolidated into BIDS to increase the automation of the process (see response to Recommendation 4). APHIS' management controls are designed to assure that inspectors complete reports for all inspection assignments and that compliance officers review these reports and follow up with appropriate correspondence or enforcement actions when noncompliance incidents are reported.



OIG Position. We agree with the planned corrective action. To reach management decision, APHIS needs to provide timeframes for implementation of BIDS.

Finding 6

Field Test Progress Reports Are Not Adequately Monitored

In addition to inspections, APHIS monitored compliance with field test regulations during 2002 and 2003 by requiring various reports from permit and notification holders during the field test. These reports contain important information on the status of the field test site and the results of the field test, including any detrimental environmental impacts. We found, however, that APHIS had not established an adequate system to monitor the receipt of required progress reports by permit and notification holders. Without such a system, APHIS cannot effectively follow up on, or assess penalties for, missing and late reports. Unless APHIS receives, tracks, and reviews all required reports from permit and notification holders, progress reporting does not serve its purpose as a control to monitor compliance with field test requirements.

APHIS regulations require all permit and notification holders to submit a field test data report within 6 months of termination of the field test.³⁶ The field test data report, also called the 6-month report, documents the methods of observation, resulting data, and analysis of any deleterious effects on plants, other organisms, or the environment. Based on the biotechnologist's review of the application and experience with the applicant and the specific crop, some approved permit applicants are also required to submit planting notices, 4-week/28-day reports, or harvest/termination notices. The planting notice indicates when a crop is about to be planted; the 4-week/28-day report provides more detailed information about the field once it is planted; and the harvest/termination notice notifies APHIS when the field is to be harvested or the field test terminated, indicating the start of the monitoring period.

³⁶ 7CFR 340.3(d)(4) and 7 CFR 340.4(f)(9), dated January 1, 2003, state that field test reports must be submitted to APHIS within 6 month "after termination of the field test." Since APHIS guidance was unclear, and the regulation states "termination of the field test," we determined the due date using field destruction dates (when that data was available) and harvest dates (when no field destruction date was available).



Reports Not Submitted or Submitted Late

Our analysis of required reporting for high-risk pharmaceutical and industrial permits, other permits, and notifications in our sample found that applicants did not always submit progress reports in a timely manner, if at all. To determine reporting requirements, we reviewed regulations, permit conditions, and/or supplemental permit conditions for our sample sites.³⁷

Pharmaceutical/Industrial Permits

For all pharmaceutical and industrial permits, approved applicants are required to submit field test data reports; all pharmaceutical and industrial permits also require planting notices and/or harvest notices, and most require 4-week/28-day reports. We reviewed required reports for 1 industrial and 12 pharmaceutical permits for 22 field test sites³⁸ and found that APHIS could not produce 11 of the 20 field test data reports (55 percent) due from pharmaceutical and industrial permit holders. Our review also showed that APHIS could not produce 36 percent of the planting notices, 10 percent of the 4-week/28-day reports, and 45 percent of the harvest notices that were due from the permit holders.

- Other Permits

All of the other permits in our sample required field test data reports, but only some required planting notices, 4-week/28-day reports, and/or harvest notices. We reviewed a total of 52 field test sites authorized under 18 other approved permits and found that APHIS could not produce 24 of the 43 field test data reports that were due (56 percent). Of the 52 field test sites, APHIS required planting notices for 48 sites, 4-week/28-day reports for 2 sites, and harvest notices for 47 sites. APHIS did not receive 10 of 47 (21 percent) of the planting notices and 16 of 41 (39 percent) of the harvest notices due. However, APHIS did receive all required 4-week/28-day reports.

- Notifications

Finally, we reviewed documentation for a total of 113 field test sites for 88 approved notifications. Regulation requires approved applicants for notifications to submit a field test data report to APHIS. Our analysis showed that 11 of 73 (15 percent) of the field test data reports due were not submitted to APHIS. Of the 62 reports ($73 - 11 = 62$) that were

³⁷ At each sample site, we reviewed the site's planting records and GEO field releases (plantings) for FYs 2002 and 2003. We then reviewed records for these additional field releases to determine reporting requirements. Thus, the results of our review include our complete sample plus our review of the documentation of additional plantings identified during our field visits. Finally, we reviewed information collected at APHIS, information collected at the field sites during our visits, and information provided by APHIS to determine which required reports had been received by APHIS.

³⁸ Because APHIS does not keep track of how many field test sites are planted under permits and notifications, we determined individual field test sites associated with permits and notifications based on our sample universe and information obtained during field site visits.



submitted, 28 of 62 (45 percent) were submitted late. Six-month field test data reports were not due on 33 notification sites during the time of our fieldwork. There was not enough information for us to make a determination on seven notification sites. Our analysis is summarized below:

Analysis of Required Reports for 113 Field Test Sites under Notifications	
11	Not submitted
28	Submitted late
34	Submitted on time (62 - 28 = 34)
33	Not due
7	Unable to determine
113	Total field test sites with required reports

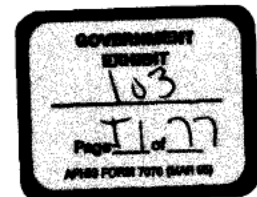
Current Database Inadequate to Track All Required Reports

Our analysis of applicant reporting disclosed that APHIS does not have an effective method, manual or computerized, to determine when or if required progress reports are submitted. APHIS' manual filing system does not lend itself to tracking receipt of reports. According to APHIS officials, progress reports for notifications are also logged into the computer system APHIS uses to store field test information. The database has a field to track the date of receipt of the 6-month field test report for notifications, but only one date and, thus, only one field test data report can be tracked, even though many notifications cover numerous field test sites. For permits, APHIS does not track the date of receipt of the 6-month field test report and other required reports in the database. APHIS officials informed us that an updated database capable of tracking field test progress reports for both permits and notifications is being developed, and it is expected to be implemented in the fall 2005.

Unclear Due Date for Field Test Data Report

Our analysis of missing and late reports was further complicated by the unclear due date for the field test data report. According to regulations, the field test data report (commonly referred to as the 6-month report) is due within 6 months after termination of the field test.³⁹ This could be interpreted as 6 months after harvest, 6 months after destruction of the field test site, 6 months after the termination of the last field test (if more than one test is being performed under a permit or notification), or 6 months after the permit or notification expires. APHIS defines termination as either harvest of the crop or destruction of the fields planted under each permit or notification

³⁹ 7 CFR 340.3(d)(4) and 7 CFR 340.4(f)(9), dated January 1, 2003



number. On occasion, APHIS has also allowed the report to be submitted within 6 months after the expiration of the permit or notification, enabling applicants with multiple field sites under a single permit or notification or number to combine the information from all plantings into one report. However, in order to be able to track submission of the field test data report, APHIS needs to clearly define "termination of the field test" and establish a firm due date for the report.

Further Coordination Between BRS and PPQ Needed

The weaknesses in coordination between BRS and PPQ, discussed in the previous finding, were further exemplified by problems tracking required reports. As a condition of the permit, some permit holders were instructed to provide planting and harvest/termination notices to the PPQ regional offices instead of directly to BRS. One PPQ regional manager recorded some information from the planting and harvest notices into his own computer system. However, this information was not submitted to BRS, and BRS never requested the information. To track receipt of required planting and harvest notices, APHIS needs a management information system that captures all critical information related to the field test process and is available to authorized personnel to monitor compliance with performance standards. In 2005, BRS began working to implement changes that will result in all reports coming to BRS directly.

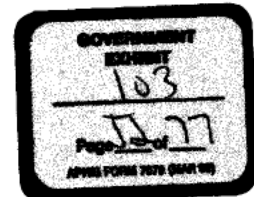
Available Sanctions Not Imposed

Regulations⁴⁰ and permit conditions allow APHIS to withdraw a permit or deny future permits if conditions of any permit have not been met. We found that APHIS has not been applying this sanction to applicants who are in violation of regulations or permit conditions by not submitting required reports on or before the dates they are due. APHIS also does not always follow up on reports of violations by applicants.

For example, APHIS' ineffective management information system allowed the issuance of 4 permits and 947 notifications to Applicant A from April 2002 through July 2004, even though it was in violation of permit conditions by not submitting required planting notices for 1 permit. Similarly, APHIS issued 68 notifications and 2 new permits to Applicant B despite its failure to file required planting and harvest notices for 3 previous permits; Applicant B also did not ensure that APHIS received the field test data reports in a timely manner. In another example, APHIS did not follow up on a violation reported three times by Applicant C. Applicant C violated the regulations by planting regulated articles without a permit.⁴¹

⁴⁰ 7 CFR 340(g), dated January 1, 2003

⁴¹ 7 CFR 340.0(a)(1), dated January 1, 2003



As long as APHIS does not assess penalties for some violations of field test regulations and permit conditions, some approved applicants may become complacent at times about following regulations.

Recommendation 19

Finalize the database for recording all information related to field test progress reports for permits and notifications, including planting notices, harvest notices, and cancellation notices, to identify violations.

Agency Response.

APHIS stated that, in its response to Recommendation 4, BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, BIDS, is fully developed and only awaits final review by the Office of the Chief Information Officer.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide specific timeframes for implementation of the corrective actions described.

Recommendation 20

Clarify guidance to define the term "termination of the field test" and establish a firm due date for field test data reports.

Agency Response.

APHIS stated that beginning in 2006, BRS will communicate to notification and permit holders clarified guidelines regarding the due dates for field reports and our use of the phrase "termination of the field test."

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide timeframes for completion of the corrective actions described.



Recommendation 21

Establish and implement controls that require all reports (inspection and progress) be submitted to BRS for tracking and review.

Agency Response.

APHIS stated that BRS addressed this issue in Recommendations 4 and 18. The problems cited by OIG are currently addressed by an interim system already in place. A system tracking permit and notification inspection and field data reports, BIDS, is fully developed and only awaits final review by the Office of the Chief Information Officer.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide the implementation date of BIDS.

Recommendation 22

Prescribe procedures for following up on missing and late progress reports.

Agency Response.

APHIS concurs with this recommendation. The problems cited by OIG are currently addressed by an interim system already in place. The database that tracks completion of field reports and inspections (BIDS) has been developed to identify missing/late reports to compliance staff (see responses to Recommendations 4 and 6).

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide the implementation date of BIDS.

Recommendation 23

Impose sanctions for missing and late progress reports.

Agency Response.

APHIS stated that BRS already considers a range of responses to missing or late reports that are progressive and are proportional to the nature and magnitude of the violation, up to and including revocation of existing permits or denial of future permits.



OIG Position.

We can not accept APHIS' management decision for this recommendation. To reach management decision, BRS needs to provide us with written policies and procedures delineating when it will impose sanctions and what actions it will take, if reports are missing or late.

Finding 7

APHIS Lacks Controls Over Final Disposition of GE Pharmaceutical Harvests

APHIS did not ensure that permit holders actually dispose of GE pharmaceutical and industrial harvests as indicated on the permit application—either through devitalization, shipment to another location, or replanting. Because APHIS controls were not effective to detect whether disposition of pharmaceutical harvests was timely, we found two sites where a pharmaceutical permit holder⁴² stored large quantities of pharmaceutical crops for over a year without APHIS' knowledge. Until APHIS requires applicants to disclose the date and details of final disposition, harvests of pharmaceutical and industrial crops could be shipped or disposed of improperly, possibly entering the food supply or the environment.

APHIS regulations⁴³ require permit applications to include a detailed description of the proposed method of final disposition of the GE crop. However, the regulations do not require applicants to disclose when the disposition will occur. They also do not require permit holders to submit periodic post-harvest reports to update APHIS on the quantity and location of GE material in storage and whether or not the disposition has actually occurred.

We found that two large harvests of GE pharmaceutical crop were stored for over a year by Applicant F cooperators (farmers conducting field tests for Applicant F), even though the permits did not contain information about the storage period so that it could be assessed by APHIS. During our field site reviews, we found that an Applicant F cooperator stored more than half a ton of a GE pharmaceutical crop for 15 months. In another State, 1.4 tons remained in storage at the cooperator's farm for 17 months. The cooperators said that they were waiting for instructions from Applicant F, who eventually instructed them to ship the harvests back to their headquarters. Although the permit applications for the field tests in these two States disclosed that the harvests would be shipped back to Applicant F's headquarters, they did not indicate when the shipments would occur. Thus, the lengthy storage of the pharmaceutical harvests was not approved by APHIS and the safety protocols

⁴² Sample field sites that planted pharmaceutical crops in 2002

⁴³ 7 CFR 340.4(b)(14), dated January 1, 2003



of the storage facilities could not be assessed. Also, PPQ did not perform inspections during the extended storage to ensure that the GE crops were safely contained in the facilities.

Furthermore, we noted that APHIS' official records contained no reports from Applicant F indicating that the harvests were in storage. APHIS needs information to determine whether approved applicants are fulfilling permit conditions for high-risk GE crops. Specifically, APHIS must require reports of significant events, including harvest amounts, storage locations, and final disposition, whether by devitalization, shipment, or replanting. Proper periodic reporting would identify violations of performance standards and increase assurance that regulated GEOs will not be inadvertently released.

Recommendation 24

Require applicants to disclose in the permit application when they plan to dispose of GE pharmaceutical and industrial harvests.

Agency Response.

APHIS stated that BRS will request this data to be provided in the field report submitted 21 days prior to harvest, as opposed to inclusion in the permit application, because projected dates are more accurate closer to the end of the growing season.

OIG Position.

We can not accept APHIS' management decision for this recommendation. To reach management decision, APHIS needs to establish written policies that require, as a supplemental permit condition, the date of disposition in the field report submitted 21 days prior to harvest and require APHIS' biotechnologists to document their review and approval of the disposition date.

Recommendation 25

Require PPQ officers to determine, when conducting post-harvest inspections, if any regulated GEOs are stored and are adequately contained.

Agency Response.

APHIS stated that inspecting for onsite storage of regulated GE plants is currently a part of our post-harvest inspections. In addition, the worksheet for post-harvest inspections that has been in use for several years includes questions about seed storage and security. Therefore, this recommendation has already been implemented.



OIG Position.

We accept management decision for Recommendation 25. To achieve final action, APHIS needs to send the Office of the Chief Financial Office, Planning and Accountability Division, its current post-harvest inspection worksheet.

Recommendation 26

Require permit holders to timely report the amount, location, and actual disposition of pharmaceutical and industrial GE harvests, including devitalization, shipment to another location, or replanting.

Agency Response.

APHIS agrees, in part, with this recommendation. APHIS will require additional information about the disposition of materials derived from plants engineered to produce pharmaceutical and industrial compounds, including expected timeframes for devitalization. However, requirements for reports on final dispositions are not necessary to ensure confinement measures are met, because this information is already captured in permit conditions and preharvest reports.

OIG Position.

We can not accept APHIS' management decision for this recommendation. APHIS is responsible for regulating biotechnology and, therefore, should know where regulated GE pharmaceutical harvests are being stored and when final disposition occurs. Permit conditions and preharvest reports can provide only estimated dates of final disposition, not actual dates. To reach management decision, APHIS needs to establish procedures that require permit holders to report the amount and location of pharmaceutical harvests and the date of final disposition.



Finding 8

GE Crops Were Not Promptly Destroyed

Due to a lack of APHIS guidance, applicants did not devitalize GE crops promptly at the conclusion of three field tests in our sample. Neither APHIS regulations⁴⁴ nor the APHIS "User's Guide for Introducing Genetically Engineered Plants and Microorganisms" specify the timeframe for devitalizing GE crops after they are no longer needed for research. If GE crops are not devitalized in a timely manner, there is a risk they could be dispersed in the environment by wind or other elements, field personnel or visitors, farm equipment, or foraging birds and other animals.

APHIS regulations⁴⁵ state that, at the conclusion of the field test, no viable material should remain that is likely to volunteer in subsequent seasons, and that volunteers must be managed to prevent persistence in the environment. Devitalization ensures that the crops do not persist in the environment and produce offspring. Methods of devitalization include:

- incorporating into the soil for decomposition;
- treating with a herbicide;
- mulching or chipping;
- exposing to high temperatures by autoclaving, baking, or incineration;
- exposing to the winter elements (e.g., potato tubers); or
- composting at a monitored location.

Although nothing came to our attention to suggest that specific instances of delayed devitalization had negative impacts on the environment, the following three examples found during our field test site visits demonstrate the need to establish timeframes for devitalization based on a case-by-case analysis of risk. All three fields were planted under notifications.

Destruction of GE Crop Delayed

Twenty days after harvest, we found a GE edible crop still in the field. Although company personnel had harvested the crop on August 20, 2003, some of the crop was left, cut in half with seeds exposed or lying still whole in the field on September 9, 2003. The following day, September 10, the company disced the remaining crop once to devitalize it. Discing left the crop in pieces, exposing more seeds than on September 9.

⁴⁴ 7 CFR 340.3 and 7 CFR 340.4, dated January 1, 2003

⁴⁵ 7 CFR 340.3(c)(6)(i) and (ii), dated January 1, 2003



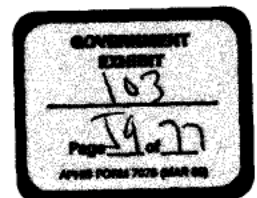
On October 27, 2003, a company representative advised that they had disced the crop further, so that the field was clean by October 21, 2003. The representative also stated that the field would be monitored for volunteers for a year after harvest. According to the representative, discing is a normal practice and has been accepted for many years by APHIS. From 1997 to 2003, APHIS approved one permit and several notifications for the company's GE research. However, we concluded that delayed discing increases the likelihood that birds or other animals would carry off some of the exposed seeds from the field. In that case, monitoring the field would not prevent the persistence of the GE crop elsewhere in the environment.

GE Crop Left in Field

On September 10, 2003, we found a GE crop, which had reportedly been cut down sometime between August 13 and August 31, 2003, lying exposed in a field. The crop had formed two border rows that acted as a "pollen sink," trapping pollen from an adjacent GE field trial. As a pollen sink, the border rows were considered GE crops and should have been devitalized promptly. Instead, the cut rows were left lying on top of the field, as shown in the following photograph. According to an APHIS official, allowing GE crops to lie in the field increases the likelihood that wind and other agents will disperse seeds from the plants.



Destroyed east border row, September 10, 2003



GE Crop Left in Compost Pile for up to 6 Months

For up to 6 months at a time, GE plants and their produce remained piled in a composting area at Applicant G. They were left to dry out so they could be burned.

In June 2000, the scientist responsible for the field test sent a copy of the protocols to APHIS, at APHIS' request. According to the protocols, "stalks of individual plants will be severed at the soil line, allowed to dry and removed to a collection pile for subsequent burning. [Produce] will be collected periodically and buried or burned." The protocols did not disclose the length of the delay between collecting and devitalizing the produce. In August 2003, the scientist revised the devitalization protocols, but, like the 2000 protocols, the new protocols did not disclose the length of the delay between piling the GE plants and produce in the composting area and devitalizing them.

According to an applicant representative, rats eat the produce, leaving small holes, but do not bite deeply enough to reach the seeds.

Recommendation 27

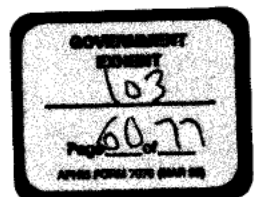
Establish and implement timeframes for devitalizing GE crops.

Agency Response.

APHIS agrees with this recommendation. APHIS is committed to developing written standards that specify expected timeframes for devitalization. APHIS has already started the process of developing the science-based standards and will continue to work on this issue to ensure full implementation by early 2006.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide specific timeframes for implementation of the corrective actions described.



Section 4. Enforcement Actions

A key component of APHIS' regulatory program is its ability to take enforcement action in response to violations of field test regulations. If APHIS detects violations of field test requirements through inspections, or if permit and notification holders fail to submit field test reports, APHIS may take enforcement action. However, we found that APHIS needs to update its regulations to ensure that, if a violation occurs, it will be handled swiftly and effectively.

Impacting its enforcement authority, APHIS' current regulations do not require permit and notification applicants to provide proof of financial responsibility. Thus, in the event of an unauthorized GEO release or other compliance infraction, USDA may have to assume financial responsibility for removing regulated GE crops from the environment or the food supply.

Finding 9

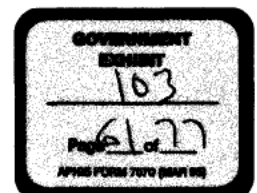
Applicants Are Not Required to Provide Proof of Financial Responsibility

APHIS approves applicants to conduct field tests without ensuring they will be able to pay the costs associated with an unauthorized GEO release or other compliance infraction. As a result, USDA may have to assume financial responsibility for removing regulated GE crops from the environment or the food supply.

Under current laws and regulations, applicants for permits or notifications are not required to provide proof of financial responsibility as part of the approval process. However, the following two high-profile incidents highlight the need for APHIS to obtain proof of financial responsibility from applicants prior to approving introductions of regulated GE crops.

In 2002, for example, Applicant D failed to properly monitor field test sites in two States where a pharmaceutical crop had been planted the previous year. PPQ inspectors found volunteer stalks of the GE crop in both fields, which had been replanted with soybeans. In one State, BRS decided to harvest and destroy the conventional crop planted within a 1,320-foot radius of the soybean field, a total of 155 acres, in case the pharmaceutical crop volunteers had been flowering at the same time as the surrounding conventional crop.

In another State, the soybean field was harvested before the pharmaceutical crop's volunteers were removed from the field. APHIS ordered Applicant D to hold the harvested soybeans while USDA supervised the destruction of the GE volunteers still in the field. Instead, the harvested soybeans were



delivered to an elevator, where they were commingled with other harvests. As a result, USDA purchased approximately 500,000 bushels of soybeans that may have commingled with the GE volunteers. Costs to acquire the soybeans were estimated at \$2.75 million to \$3.75 million. Subsequently, Applicant D agreed to provide proof of financial responsibility consisting of either a deposit of money, liability insurance, or a surety bond before APHIS approval of any future field testing; to pay a civil penalty of \$250,000; and to reimburse USDA for costs incurred at the field test site in one of the States.

Also in 2002, Applicant E filed for bankruptcy and, according to a former employee, went out of business, during the postharvest monitoring period of a field test of a GE pharmaceutical crop. Applicant E never paid the cooperator who was conducting the field test on the company's behalf, and APHIS agreed that the cooperator was not legally responsible for monitoring the field for volunteers. Although the cooperator agreed to monitor the field, APHIS may not be able to obtain such assistance in all cases.

An Office of the General Counsel official advised us that APHIS currently does not have legislative authority to hold applicants financially responsible for costs incurred by USDA due to unauthorized releases of regulated GEOs. In light of the incidents described above, APHIS should seek legislative authority to require permit applicants to provide proof of financial responsibility to indemnify USDA for costs incurred due to an unauthorized release of a GEO. The required proof of financial responsibility should be based on the level of risk of the GEO and other risk factors, such as the applicant's experience with the type of GEO and APHIS' past experiences with the applicant.

Recommendation 28

Seek legislative change to obtain the authority to require permit applicants, based on the level of risk, to provide proof of financial responsibility, in the event of an unauthorized GEO release.

Agency Response.

APHIS stated that it does not have the authority to accept this recommendation. It will, however, refer the matter to the Office of the Secretary, for a policy decision, and further action as appropriate, within 30 days.

OIG Position.

We agree with the planned corrective action. To reach management decision, APHIS needs to provide us with the policy determination made by the Office of the Secretary.



Scope and Methodology

Our audit was conducted at APHIS/BRS headquarters located in Riverdale, Maryland; the PPQ Western Regional Office in Ft. Collins, Colorado; and 91 field test sites in 22 States. Our audit was conducted between May 2003 and April 2005.

We initiated this audit as a result of an audit survey conducted in 2001 of the Department's controls over the release of GEOs into the environment. Based on our fieldwork, we identified a number of systemic weaknesses in the regulation of field releases of GE crops. Our survey revealed weaknesses in the approval process for field releases, field site inspections, and interstate movements of regulated GEOs.

We selected 107 field test sites (comprised of 69 permit sites and 38 notification sites) from a universe of 1,020 field test sites (comprised of 32 permits and 228 notifications) located in the continental United States and Hawaii. We were unable to inspect 30 sites because they were not planted and another 8 because they had been harvested. We then substituted 22 additional sites from our universe for a total of 91 sites (53 sites under 23 permits and 38 sites under 28 notifications).

Our initial universe of 1,020 field test sites planted or to be planted with regulated GE crops consisted of 982 fields with expected harvest dates during or after September 2003, and 38 fields planted with pharmaceutical GE crops in 2002, which were to be reinspected for volunteers in 2003. Since APHIS did not maintain a list of planted GE fields, we developed our universe by:

- obtaining a list developed by APHIS of fields planted with pharmaceutical crops in 2002 that were to be reinspected for volunteers in 2003;
- identifying companies with pharmaceutical permits approved in 2001 and 2002 from lists provided by APHIS;
- identifying companies with permits renewed or amended in 2001, 2002, and 2003 from a list provided by APHIS;
- contacting the companies for information about the regulated GE fields that they planted or planned to plant from January 1, 2003, through September 30, 2003;
- reviewing reports from USDA/Agricultural Research Service's database to identify research that might include field trials of regulated GE crops;
- asking the USDA/Agricultural Research Service to contact our tentative selection of applicants to obtain information about whether they had



planted regulated GE crops from January 1, 2003, through September 30, 2003;

- reviewing reports in the Current Research Information System⁴⁶ to identify research that might include field trials of GE crops;
- asking APHIS to review our tentative selection of the Current Research Information System projects to determine whether the research was regulated by APHIS; and
- asking APHIS to contact the approved applicants (of the regulated Current Research Information System projects) to obtain information about whether they had planted regulated GE crops from January 1, 2003, through September 30, 2003.

During the audit, we also drew six separate judgmental samples.

- 199 movements made to or from the sampled field test sites in 2002 and 2003 to determine whether applicants complied with regulations for movement of GE regulated articles. The documentation was obtained from the personnel at the sampled field sites.
- 10 official files for pharmaceutical GEOs planted in 2002 to review the evidence of BRS scientific reviews. We judgmentally selected the files from a list that BRS provided showing 2002 pharmaceutical sites that were to be reinspected in 2003.
- 90 notifications to determine whether applicants were required to have written protocols at the field sites.
- 22 field test sites for pharmaceutical and industrial permits to determine if permit holders were complying with APHIS reporting requirements.
- 52 field test sites for other permits to determine if permit holders were complying with APHIS reporting requirements.
- 113 field test sites for notifications to determine if field test data reports were submitted to APHIS.

Our audit was performed in accordance with Generally Accepted Government Auditing Standards. To accomplish the audit objectives, we performed the following steps:

- applicable laws, regulations, and guidance concerning regulated GE crops;
- reviewed APHIS policies, procedures, and controls concerning GE crops;
- interviewed BRS Headquarters and PPQ regional officials;
- visited field test sites where regulated GE crops were planted;
- interviewed PPQ officers and persons conducting field tests; and
- interviewed cooperators regarding field release operations under permits and notifications.

⁴⁶ A public database administered by USDA's Cooperative State Research, Education, and Extension Service



Exhibit A- Agency Response

Exhibit A – Page 1 of 10



APHIS Response to 50601-8-TE

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and
Plant Health
Inspection
Service

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Room 317 EW
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20250

TO: Robert W. Young
Assistant Inspector General for Audit

FROM: W. Ron DeHaven
Administrator

Kevin Shea 16r

NOV 2 2005

SUBJECT: APHIS Response to OIG Report, "Controls
Over Issuance of Genetically Engineered
Organism Release Permits (50601-8-TE)"

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on this report. We have provided overall comments about the role and responsibilities of APHIS' Biotechnology Regulatory Services (BRS), and specific comments about the report's findings and recommendations.

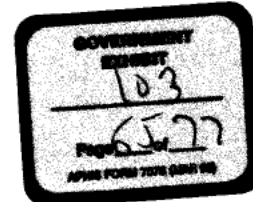
APHIS is committed to protecting U.S. agriculture and ensuring the safety of the nation's food supply. As a part of this responsibility, APHIS established BRS in 2002, to elevate the Agency's focus and priority on biotechnology regulatory activities. It is the role of BRS to rigorously and appropriately regulate genetically engineered (GE) organisms to ensure that they are just as safe for agriculture and the environment as traditionally bred crop varieties, which have been the cornerstone of American agriculture. Further, since its establishment, BRS has set a clear direction to strengthen the regulatory process, to ensure safety by using the best science available to evaluate risks, and to support the process with a strong compliance and enforcement program.

The findings and recommendations in the Office of Inspector General's (OIG) report affirm the direction BRS set for itself and the many actions BRS has taken to accomplish its goals. Although OIG began its review in April of 2003, less than a year after BRS was created, the early direction set by BRS has enabled them to complete or begin implementing twenty-three of the twenty-eight recommendations in the OIG report. BRS has:

- Gained interagency agreement on the focus of a historic revision of APHIS biotechnology regulations and published a Notice of Intent to prepare a program-wide Environmental Impact Statement (EIS) with a proposed rule to follow that will reflect experiences gained and position BRS to meet the challenges ahead;



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APHIS Response to 50601-8-TE

- Conducted more than two dozen stakeholder group meetings to solicit input for the EIS and revised regulations, held a workshop regarding the reduction of regulatory burdens for specialty crops and to further engage the states, hosted a workshop with the National Association of State Departments of Agriculture (NASDA) and established a cooperative agreement with the National Plant Board (NPB) to provide mechanisms for early state input on Federal biotechnology regulatory issues;
- Established a compliance and enforcement branch, with a dedicated team of headquarters and regional compliance officers, to ensure that all those involved in the field testing of GE crops understand and adhere to the regulations set forth by the program;
- Established a Memorandum of Understanding (MOU) with APHIS' Plant Protection and Quarantine (PPQ) to formalize inspection responsibilities, better coordinate inspections in respective regions, enhance technical assistance and training to inspectors, and ensure inspections are completed in a timely manner;
- Revised procedures to document a formal, risk-based criteria process to determine which field tests are inspected, as well as performance standard checklists and to revise program inspection manuals;
- Enhanced tracking procedures to improve efficiency and better document inspection activities, planting requirements, and other key information, as well as designed a single database to consolidate information related to field tests and provide a central warehouse of information for BRS;
- Designed a consolidated and updated *Biotechnology Regulatory Services User's Guide* (User's Guide) for the regulated community and interested public, which will incorporate all existing guidance materials into a single, accessible, easy-to-understand resource and clarify BRS policy and procedures.

Since 1987, APHIS has safely regulated GE organisms and provided oversight and enforcement for over 10,000 field tests with no demonstrable negative environmental impacts having arisen from these tests. To assure field tests are safely carried out, APHIS uses long accepted science-based principles, confirmed by the National Academy of Sciences, for the safe introduction of GE organisms.

APHIS recognizes that even successful programs can be improved and that change is necessary to keep current with changing technological trends. To that end, APHIS appreciates the work of the OIG in developing this report and the recommendations contained within. Below are our responses to the findings and recommendations.



APHIS Response to 50601-8-TE

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Recommendation 1: Revise and consolidate policies, procedures, and regulatory requirements for GE field releases.

APHIS Response: This recommendation is consistent with the priorities set by BRS, including the revision of its regulation to incorporate the experience gained through nearly 20 years of regulation and the provisions of the Plant Protection Act of 2000. In 2003, BRS participated in a formal interagency discussion and coordination process with various Federal agencies including the Coordinated Framework Agencies (i.e., FDA, EPA). At the conclusion of this process, BRS gained inter-agency agreement on key aspects of APHIS' regulation revisions. BRS initiated the process of revising its regulations in January 2004 by publishing a Notice of Intent to prepare a program-wide Environmental Impact Statement (EIS). BRS will publish a draft Programmatic EIS in early 2006 and a proposed rule will follow. Rules are developed through public notice and comment, and therefore can take several years for completion. However, APHIS is committed to revising the rule. In addition, BRS has begun the consolidation and revision of guidance materials into a single *User's Guide*, and expects to have a draft version completed in the spring of 2006.

Recommendation 2: Revise and clarify policies and regulations regarding the use of metal shipping containers.

APHIS Response: As part of the new direction set by BRS, clarification of shipping container requirements for permits and notifications will be covered in the revised regulations. In addition, this issue is being addressed by the development of a consolidated and revised *User's Guide*. Again, BRS has begun the consolidation and revision of guidance materials into a single *User's Guide*, and expects to have a draft version completed in the spring of 2006.

Recommendation 3: Update regulations to incorporate the provisions of the Plant Protection Act of 2000.

APHIS Response: An early priority established by BRS was the revision of its regulation to incorporate the provisions of the Plant Protection Act of 2000 and to reflect the experience and knowledge gained through years of regulating biotechnology. In 2003, BRS participated in a formal interagency discussion and coordination process with various Federal agencies including the Coordinated Framework Agencies (i.e., FDA, EPA). At the conclusion of this process, BRS gained inter-agency agreement on key aspects of APHIS' regulation revisions. In January 2004, BRS published a Notice of Intent to prepare a program-wide Environmental Impact Statement (EIS) which lays the foundation for a proposed rule that will include provisions of the Plant Protection Act of 2000. BRS has conducted more than two dozen stakeholder group meetings to solicit input for the EIS and regulatory revisions, hosted a workshop with the National Association of State Departments of



APHIS Response to 50601-8-TE

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Agriculture (NASDA) and established a cooperative agreement with the National Plant Board (NPB) to provide mechanisms for early and systematic state input into BRS' regulatory revision process. BRS will publish its draft Programmatic EIS in early 2006, with a proposed rule to follow. BRS is committed to the completion of the process of revising the rule.

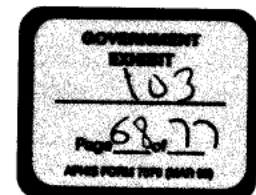
Recommendation 4: Prioritize completion of the management information systems to track all information on permits and notifications.

APHIS Response: Since the creation of BRS, the completion of comprehensive state-of-the-art management information systems has been a high priority for APHIS. BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, the Biotechnology Integrated Database System (BIDS), is fully developed and only awaits final review by the Office of the Chief Information Officer.

Recommendation 5: Develop policy guidelines that address restricting public access to edible regulated crops when conducting field tests.

APHIS Response: APHIS disagrees with this recommendation. APHIS understands that the intent of this recommendation is to assure food safety. However, we feel that the system of science-based risk assessment that we currently have in place already addresses this issue. BRS can, for example, use permit conditions to require restricted access for any special cases where it might be deemed appropriate based on risk. The need for restricted access is most effectively addressed on a case-by-case basis where the biotechnologist can consider the type of trial, potential risks of the organism, and other information specific to the permit such as the exact site and locale.

Within the United States government, FDA has authority over the safety of plant foods, including foods from GE plants. EPA has authority over the safety of pesticide components in GE plants that are engineered to express proteins intended to protect the plants from insects or diseases. Food and agriculture biotechnology policy is coordinated through the Office of Science and Technology Policy (OSTP) under what is known as the Coordinated Framework for Biotechnology. The agencies regularly discuss various aspects of food and agriculture biotechnology oversight, either through OSTP-led meetings or communication at the technical level. Through those processes, FDA and EPA are kept apprised of APHIS' requirements for field testing of bioengineered food crops, including crops that have not undergone or completed



APHIS Response to 50601-8-TE

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all applicable food safety review, and have supported the APHIS requirements and practices for such crops.

Recommendation 6: Revise regulations to require all permit and notification holders to submit planting notices, 4-week/28-day reports, and harvest/termination reports for all field test sites.

APHIS Response: BRS has already strengthened reporting guidelines for notifications in the 2005 growing season and is currently evaluating the various field report requirements for permits and notifications with the conclusions to be reflected in the new regulations. APHIS agrees in part with this recommendation but disagrees with the requirement for planting notices for the notifications because these notices are necessary only in cases where a pre-plant inspection is warranted. With the completion of the new regulations, BRS will require the 4 week/28 day reports for all field tests. Thus, BRS will know what has been planted within 28 days for all field tests and BRS already requires reports six months after harvest/termination.

Recommendation 7: Revise regulations to require all permit and notification holders to submit the GPS coordinates of field test sites on all reports submitted after planting.

APHIS Response: This recommendation is consistent with the direction set by BRS and in fact, BRS has already requested that GPS coordinates of each field site be submitted in 28-day planting reports. Additionally, BRS is incorporating field test location information requirements into its regulatory revisions.

Recommendation 8: Revise regulations to require all permit and notification holders to submit notices of decision not to plant if they decide to cancel an approved field test location.

APHIS Response: BRS has made revision of its regulations a priority and this issue will be addressed as part of that process. Currently, this information is already requested of all growers through our guidelines.

Recommendation 9: Complete work on the management information system and ensure that it is capable of recording necessary information related to the field test sites including the specific location of each field site and the dates of significant events.

APHIS Response: See response to Recommendation 4. A comprehensive and state-of-the-art management information system was identified as an early priority for BRS



APHIS Response to 50601-8-TE

Page 6

and BRS has made much progress on this initiative. In fact, our new database system is already designed to capture all of the OIG recommended information and more.

Recommendation 10: Amend regulations to require applicants for notifications to submit written protocols prior to approval of the field test.

APHIS Response: APHIS disagrees with this recommendation. While we do evaluate written protocols for permits, we believe that the current system of performance-based regulatory standards for notifications is effective at protecting American agriculture. Based upon our familiarity with the crops eligible for notification, we do not feel it is warranted to require or review written protocols prior to approval of field tests. Performance-based regulatory standards are commonly used in APHIS and other regulatory agencies, and our use of this approach for notifications has been acknowledged as appropriate by the National Academy of Science. The intent of the notification procedure is to provide an administratively-streamlined process for trials of crop-trait combinations with which APHIS already has a great deal of experience and familiarity.

Recommendation 11: Require and document biotechnologist reviews of notification protocols to ensure they are sufficient to meet performance standards.

APHIS Response: APHIS disagrees with this recommendation. See response to Recommendation 10.

Recommendation 12: Distribute written protocols to PPQ officers to use in conducting inspections of field test sites planted under notification.

APHIS Response: PPQ officers currently have access to written protocols at the field test site. In addition, field test design protocols for notifications will be included in our database system (see response to Recommendation 4), which can be accessed by PPQ inspectors prior to their inspections.

Recommendation 13: Develop and implement policies and procedures for documenting the scientific process and criteria for approving applications and require supervisory review of biotechnologists' work.

APHIS Response: Another early priority for BRS was strengthening science-based risk assessment policies and procedures. BRS has developed and implemented six new standard operating procedures (SOPs) related to the scientific review process. BRS is currently formulating plans for increased documentation and supervisory



APHIS Response to 50601-8-TE

Page 7

review of the process. Many of these plans will be implemented before the end of fiscal year 2006. However, BRS believes major actions to address this recommendation will continue to be ongoing to ensure that a continual process of updating and improvement is in place. Further, the consolidated *User's Guide* under development will articulate our review process and approval criteria.

Recommendation 14: Establish requirements for the number of field site inspections to be performed for permits and notifications.

APHIS Response: BRS has always had requirements for field site inspections. The Compliance and Enforcement Branch has implemented documentation procedures for field site inspections and strengthened and clarified the requirements for the selection of field sites. We are continuing to strengthen our inspection requirements by developing new procedures for selection of field-site inspections based upon key risk-related factors, and are always updating and improving our procedures based upon our experience and new knowledge about risk-related factors. We are also considering additional inspection requirements as we develop our new regulations.

Recommendation 15: Develop and implement written policies and procedures for selecting specific field test sites for inspection based on risk.

APHIS Response: APHIS disagrees with this recommendation. Individual field trial sites within a given notification or permit are of comparable risk. Once a notification or permit has been selected for inspection by BRS risk assessment, allowing PPQ inspectors the flexibility to choose the specific inspection site within the permit or notification encourages more efficient use of government resources without compromising safety.

Recommendation 16: Clarify the specific roles and responsibilities of BRS and PPQ in the MOU regarding the selection and inspection of non-pharmaceutical and non-industrial release and movement permits.

APHIS Response: BRS and PPQ had already established an MOU that addressed BRS' inspection requirements for each type of permit, including non-pharmaceutical and non-industrial permits as well as the notifications. The MOU was originally written in a manner so that responsibilities were clear to both BRS and PPQ, and was implemented without any problems. However, OIG interpreted the language in the MOU differently, and suggested that problems could arise. BRS and PPQ have made revisions to the MOU to address your concerns.



APHIS Response to 50601-8-TE

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Recommendation 17: Finalize the inspection tracking system and ensure that it is effective in recording the receipt of inspection reports, inspection results, and the number of inspections completed.

APHIS Response: This recommendation is consistent with the priorities already set by BRS. BRS currently has a system in place to track all of the recommended data and an improved database system for tracking inspection and field data reports has now been fully developed and will be operational after a final review by the Office of the Chief Information Officer (see response to Recommendation 4).

Recommendation 18: Finalize and implement management controls to require reporting of all inspections to BRS for review and follow-up on violations.

APHIS Response: Since the creation of BRS, the completion of our management information systems has been a high priority for APHIS, therefore we agree with the recommendation. The problems cited by OIG are currently addressed by an interim system already in place. Now that these management controls are operational, they will be consolidated into the BIDS system to increase the automation of the process (see response to Recommendation 4). Our management controls are designed to assure that inspectors complete reports for all inspection assignments and that compliance officers review these reports and follow up with appropriate correspondence or enforcement actions when noncompliance incidents are reported.

Recommendation 19: Finalize the database for recording all information related to field test progress reports for permits and notifications, including planting notices, harvest notices, and cancellation notices, to identify violations.

APHIS Response: As stated in response to Recommendation 4, since the creation of BRS, the completion of comprehensive state-of-the-art management information systems has been a high priority for APHIS. BRS is implementing an ePermits tracking system that is nearly complete and is expected to be accepting electronic submissions of notifications in December 2005. It will later be expanded to accept permit applications and to give PPQ inspectors access to field test design protocols and field test conditions. A second system tracking permit and notification inspection and field data reports, the Biotechnology Integrated Database System (BIDS), is fully developed and only awaits final review by the Office of the Chief Information Officer.

Recommendation 20: Clarify guidance to define the term "termination of the field test" and establish a firm due date for field test data reports.



APHIS Response to 50601-8-TE

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APHIS Response: When BRS was established, it set a goal to be more transparent and began actions to clarify policies and guidance. As part of those efforts, beginning in 2006, BRS will communicate to notification and permit holders clarified guidelines regarding the due dates for field reports and our use of the phrase "termination of the field test."

Recommendation 21: Establish and implement controls that require all reports (inspection and progress) to be submitted to BRS for tracking and review.

APHIS Response: BRS has addressed this issue as it has been raised in Recommendations 4 and 18. See responses to Recommendations 4 and 18.

Recommendation 22: Prescribe procedures for following up on missing/late progress reports.

APHIS Response: The database that tracks completion of field reports and inspections has been developed to identify missing/late reports to compliance staff (see responses to Recommendations 4 and 6).

Recommendation 23: Impose sanctions for missing and late progress reports.

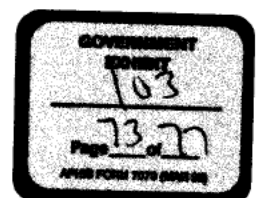
APHIS Response: BRS already considers a range of responses to missing or late reports that are progressive and are proportional to the nature and magnitude of the violation, up to and including revocation of existing permits or denial of future permits.

Recommendation 24: Require applicants to disclose when they plan to dispose of GE pharmaceutical and industrial harvest in the permit application.

APHIS Response: BRS will request this data to be provided in the field report submitted 21 days prior to harvest, as opposed to inclusion in the permit application, because projected dates are more accurate closer to the end of the growing season, therefore APHIS agrees with this recommendation, in part.

Recommendation 25: Require PPQ officers to determine, when conducting post-harvest inspections, if any regulated GEOs are stored and adequately contained.

APHIS Response: Inspecting for on-site storage of regulated GE plants is currently a part of our post-harvest inspections. In addition, the worksheet for post-harvest



APHIS Response to 50601-8-TE

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inspections that has been in use for several years includes questions about seed storage and security. Therefore, this recommendation has already been implemented.

Recommendation 26: Require permit holders to timely report the amount, location, and actual disposition of pharmaceutical and industrial GE harvests, including devitalization, shipment to another location, or replanting.

APHIS Response: APHIS agrees, in part, with this recommendation. APHIS will require additional information about the disposition of materials derived from plants engineered to produce pharmaceutical and industrial compounds, including expected timeframes for devitalization. However, requirements for reports on final dispositions are not necessary to ensure confinement measures are met, because this information is already captured in permit conditions and pre-harvest reports.

Recommendation 27: Establish and implement timeframes for devitalizing GE crops.

APHIS Response: APHIS agrees with this recommendation. APHIS is committed to developing written standards that specify expected timeframes for devitalization. APHIS has already started the process of developing the science-based standards, and will continue to work on this issue to ensure full implementation by early 2006.

Recommendation 28: Seek legislative change to obtain the authority to require permit applicants, based on level of risk, to provide proof of financial responsibility in the event of an unauthorized GEO release.

APHIS Response: APHIS does not have the authority to accept this recommendation. We will, however, refer it to the Office of the Secretary for a policy decision, and further action as appropriate, within 30 days.



Glossary of Terms

Applicant	Person who applies for a permit or notification to introduce a GEO.
Border row	A perimeter of non-GE plants surrounding GE plants at a field test site.
DNA	Deoxyribonucleic acid (DNA). The basis for genetics and heredity, DNA is found within the nucleus of most plant and animal cells.
Devitalization	Methods of rendering transgenic material nonviable (dead) and, therefore, no longer a potential plant pest subject to regulation. Methods could include dry heat, steam heat, crushing, deep burial, and/or chemical treatment.
Disposition	What becomes of the crop after the field test, including harvest for shipment or replanting, or destruction.
Field test	Planting of GE crops in the environment to test their agronomic properties.
Gene	A segment of DNA that typically codes for a protein. A gene is also a unit of heredity.
Genetic engineering	Process by which DNA from one or more organisms is inserted into the genetic material of a second organism so that the second organism (host) expresses new traits. Also called biotechnology.
Industrial plants	Plants engineered to produce industrial compounds include those plants that meet the following three criteria: (1) the plants are engineered to produce compounds that are new to the plant, (2) the new compound has not been commonly used in food or feed, and (3) the new compound is being expressed for nonfood, nonfeed industrial uses. Industrial uses include, but are not limited to, detergent manufacturing, paper production, and mineral recovery.
Introduction	Importation, interstate movement, or confined release into the environment.
Monitoring	Applicants' protocol of adequate duration to ensure all plant volunteers have been eliminated.
Movement	To ship, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States.



Notification	A streamlined procedure under APHIS regulations by which regulated articles may be introduced into the environment, such as for a field test. The notification application is submitted at least 30 days in advance of the proposed release into the environment.
Performance standards	A set of six conditions that notification holders must meet in order to ensure containment of the introduced regulated article.
Permit	A written authorization from APHIS to allow release of a regulated article into the environment. The permit application is submitted at least 120 days in advance of the proposed release into the environment.
Permit conditions	APHIS requirements that must be met to prevent the dissemination and establishment of plant pest.
Pharmaceutical plants	Any plant manipulated by recombinant DNA technology to express a gene encoding a biological or drug product.
Pollen sink	A perimeter of nontransgenic plants that surround transgenic plants and acts as a pollen sink for insect pollinators.
Protocols	Description of the methods to be used during the field test to meet the performance standards or permit/notification conditions.
Regulated article	Any organism that has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in 7 CFR 340.2, dated January 1, 2003, and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown.
Release	The use of a regulated article outside the physical constraints of a laboratory, greenhouse, fermenter, or other contained structure.
Transgene	A gene transferred into another organism by means of biotechnology.
Transgenic crop	An agricultural crop that expresses one or more transgenes.
Volunteer plants	Plants originating from seeds of a GE crop planted the previous season.



Informational Copies of this report have been distributed to:

Administrator, APHIS	
Attn: Agency Liaison Office	(9)
General Accountability Office	(1)
Office of the Chief Financial Officer	
Director, Planning and Accountability Division	(1)
Office of Management and Budget	(1)



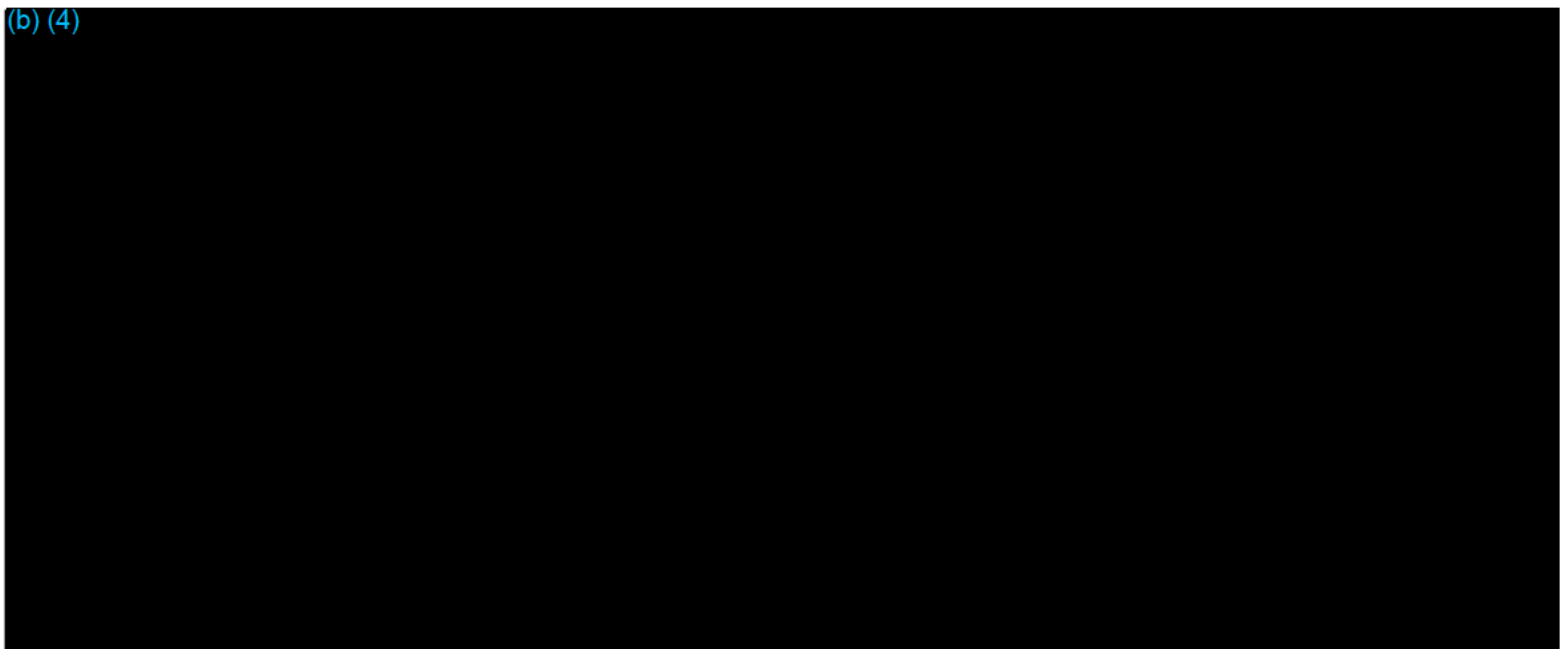
(b) (6), (b) (7)(C) - APHIS

From: (b) (6), (b) (7)(C) >
Sent: Saturday, May 25, 2013 5:01 PM
To: (b) (6), (b) (7) - APHIS
Cc: (b) (6), (b) (7)(C)
Subject: Monsanto Confidential Business Information - Seed Loss
Attachments: SeedLoss.pdf

(b)

All of the following information provided in response to this question and the attachment provided is Monsanto Confidential Business Information, where identified as CBI or Confidential Information in the records provided to the agency at the time of the incident.

(b) (4)



Thanks

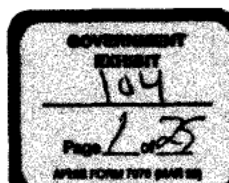
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Monsanto Company

(b) (6), (b) (7)(C)

(b) (6), (b) (7)

OR120018¹_BR_003120





United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Marketing & Regulatory
Programs Business
Services

Investigative &
Enforcement Services

2150 Centre Avenue
Bldg (b) (6), (b) (7)(C)
Ft. Collins, CO 80526

PH# (970) 494-7485
Fax# (970) 494-7487

To: (b) (6), (b) (7)(C)

From: (b) (6), (b) (7)

Date: 3/16/04

cc: (b) (6), (b) (7) ✓
(b) (6), (b) (7)

Subject: MO04015-BR Monsanto Company

The attached investigative report documents a lack of evidence to support violations of 7 CFR 340 by Monsanto Company in their loss of a small amount of regulated glyphosate-tolerant wheat seed from their growing chamber at their Chesterfield Missouri facility.

Monsanto Company conducted an internal investigation into their loss of the regulated seed and their investigation was not able to determine what happened to the wheat seeds. I interviewed the Scientist, Monsanto Department Supervisors, Monsanto Company Team Lead Biotech Compliance and Attorneys associated with the missing seeds and I inspected the seed storage site and growth chambers. I was not able to determine who may of taken the seeds from the growth chambers and if the seed ever left the Monsanto facility.

In inspecting the site I found several areas of concern. The subject regulated seeds were and are kept in a seed storage cooler with thousands of other seeds. This seed storage cooler is located on a Monsanto Company Campus with over 1000 employees. Access to this storage area is open to anyone from the Monsanto Company that holds a pass card into this building seven days a week 24 hours a day. No log is used to check seeds out or into this cooler. Access to the growth chamber where the seed was planted is also open to all Monsanto Company employees who hold a pass into their Campus Complex. Determining what happened to the missing seed in my opinion is impossible. Upon review of the 7 CFR 340 regulations they do not appear to require security measures for regulated plants and plant parts prior to release into the environment. I suggest adopting regulations that address this issue.

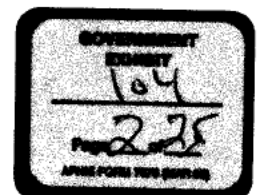
Another area of concern is the 7 CFR 340 regulations do not require reporting of lost or stolen regulated material that has not been released into the environment. I suggest adopting regulations that address this issue



Safeguarding American Agriculture
APHIS is an agency of USDA's Marketing and Regulatory Program

An Equal Opportunity Provider and Employer

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Individuals that need to be updated as this case progresses through the system.

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ARD

RD

Biotech Program Operations IES

IES

USDA APHIS

USDA APHIS

USDA APHIS

Riverdale MD

Fort Collins CO

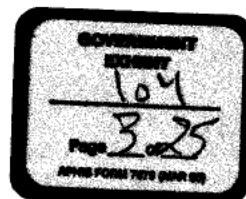
Fort Collins CO

(b) (6), (b) (7)(C)

Investigator

USDA APHIS IES

OR120018_BR_003124



UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
INVESTIGATIVE AND ENFORCEMENT SERVICES
WESTERN REGION
FORT COLLINS, CO

REPORT OF INVESTIGATION

Case Number: MO04015-BR

Alleged Violation: 7 CFR 340

Alleged Violator: Monsanto Company
700 Chesterfield Parkway North
Chesterfield Missouri 63198

Phone: (636) 737-6370

Business Information: Monsanto Company is an international company comprised of many diverse departments. For the purpose of this investigation one of the departments of Monsanto Company conducts research and produces products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests.

Summary of Events: On or about 11/02 Monsanto Company imported and received regulated wheat seeds from their Plant Breeding Station in the Czech Republic. The wheat seeds contained a genetically engineered gene referred to as CP4. On 6/12/03 Monsanto Company planted a portion of the regulated wheat seeds (1000 seeds) in a growth chamber in their facility in Chesterfield Missouri. On 9/30/03 during harvest of the plants, it was noticed that 18 wheat heads had been removed from plants. Monsanto Company immediately reported this accidental/unauthorized release to USDA APHIS and conducted an in house investigation. Their investigation has not been able to determine what happened to the wheat heads.

Explanation of Evidence: **Monsanto Company Import Notification Request Packet** (Exhibit 1) requesting the importation of Glyphosate tolerant wheat seed from the Czech Republic. **Import Notification 02-003-6n** (Exhibit 2) issued to Monsanto Company for the importation of regulated article wheat. **Monsanto Company Letter** (Exhibit 3)

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notifying their Czech Republic Plant Breeding Station of the
USDA import notification approval 02-003-06n. **USDA
Departmental Permit 62741** (Exhibit 4) issued to Monsanto
Company to import various prohibited plants and plant parts from
various countries. **Monsanto Company Compliance Packet 2002
Importation** (Exhibit 5) handwritten note documents seed
received Nov 2002 – 1 import sticker used – 4 stickers returned
Nov 19 2002. **E Mail Messages** (Exhibit 6) between Monsanto
research scientists regarding the importation of the regulated wheat
seed. **Monsanto Company Letter** (Exhibit 7) to USDA APHIS
Juan Roman notifying USDA of the potential loss of regulated
wheat seed. **(Monsanto Company Investigative Report** (Exhibit
8) outlining their investigation and finding relating to missing
regulated wheat seed.

---SEE ATTACHMENTS---

Summary: It can not be determined that a person moved or released the
regulated wheat seed into the environment. No violation occurred.

Investigator: (b) (6), (b) (7)(C)
USDA APHIS FES
2150 Centre Ave
Bldg (b) (6), (b) (7)
Fort Collins, Colorado 80526
(b) (6), (b) (7)

Date of Report: March 18, 2004

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MONSANTO



CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (314) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2001-849XC

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

1. USDA Reference Number
2. Applicant Reference Number 2001-849XC
3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO

63198

Phone
FAX
Email

(b) (6), (b) (7)(C)

636/737-7085

(b) (6), (b) (7)(C)

4. Duration of Introduction
Import

February 01, 2002 - February 01, 2003

5. Recipient
Wheat, Triticum aestivum

6. Regulated Article

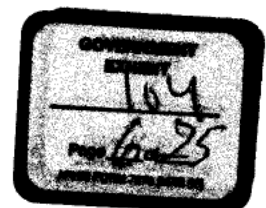
Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Bobwhite



CONFIDENTIAL

Monsanto Reference ID

2001-849XC

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2

(b) (4)

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Gene: CTP2-CP4 – A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' – A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 –

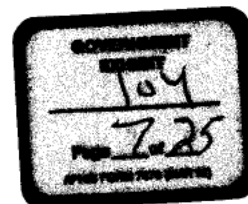
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CBI

Gene: CTP2-CP4 – A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Transcription termination sequence: NOS 3' – A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.



CONFIDENTIAL

Monsanto Reference ID
2001-849XC

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Import

Ship up to 20 pounds wheat seed to and from each location.

ORIGIN:
Czech Republic

DESTINATION:
USA

Ship From:

CR

CR, Czech Republic

(b) (4)

Branisovice County/Province, CR.

CONTACT:

CR, Czech Republic,

(b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

MO

USA

(b) (4)

St. Louis County/Province, MO,

(b) (4)

CONTACT:

(b) (4), (b) (6), (b) (7)(C)
USA,

(b) (4), (b) (6), (b) (7)(C)

MO,

] - CBI



MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

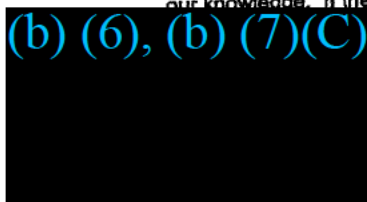
CONFIDENTIAL

Monsanto Reference ID
2001-849XC

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

Permits &
Risk
Assessments

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

January 31, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 2, 2002.

Import
Notification no. 02-003-06n (2001-849XC)
Regulated article - Wheat
Destination - Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

See the attached information on importation.

In addition, you must obtain a departmental permit. For more information, please contact Ms. Karen Brady at (301) 734-5208.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
OIC, J.F.K.I.A, Jamaica, NY



APHIS- Protecting American Agriculture

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OR120018_BR_003138

Your permit authorizes you to receive imported organisms from foreign sources and you have received labels that you must send to your supplier. Your supplier must affix an original label to each package. The labels will route the package to a PPQ Inspection Station at the port of entry into the United States.

As part of our national effort to improve biosecurity, after using one of the enclosed label(s), please e-mail us at biotech@aphis.usda.gov or via fax at Area Code (301) 734-8910 the following information. If you email us the information, please put labels in the subject line and use letterhead stationary for faxes.

The APHIS notification or permit number (e.g 01-343-01n),
your name and affiliation, and
the number of labels used and the date you received your engineered organism.

Please use the labels in numeric order. Note that they now have an expiration date.

Hand Carrying Imported Organisms

If your permit authorizes you to hand carry organisms, you must declare this material and present a copy of your authorization to inspecting officials at the U. S. port of entry. If you designate an individual to hand carry permitted organisms for you, the traveler must present inspecting officials with the following items: (1) a copy of the permit; (2) a letter on company letterhead, signed by the permittee, authorizing the traveler to hand carry the organisms; and (3) the traveler's passport or other acceptable form of identification. Upon arrival in the United States, the designated person must carry the package directly to your facility. No diversion is permitted.



GENETIC
DO NOT OPEN
OR DESIGNATE

DEL

U.S. DEPARTMENT

ANIMAL AND PLANT HEALTH
PLANT PROTECTION AND

Plant Inspection Station
Bldg. 77, JFK International
Jamaica, NY 11430-1096

APHIS FORM 2051 (JUL 89)

PERMIT NO. 02-

Expires

GENETIC
DO NOT OPEN
OR DESIGNATED

DEL

U.S. DEPARTMENT

ANIMAL AND PLANT HEALTH
PLANT PROTECTION AND

Plant Inspection Station
Bldg. 77, JFK International
Jamaica, NY 11430-1096

APHIS FORM 2051 (JUL 89)

PERMIT NO. 02-

Expires

GENETIC
DO NOT OPEN
OR DESIGNATED

DEL

U.S. DEPARTMENT

ANIMAL AND PLANT HEALTH
PLANT PROTECTION AND

Plant Inspection Station
Bldg. 77, JFK International
Jamaica, NY 11430-1096

APHIS FORM 2051 (JUL 89)

PERMIT NO. 02-

Expires

GENETIC
DO NOT OPEN
OR DESIGNATED

DEL

U.S. DEPARTMENT

ANIMAL AND PLANT HEALTH
PLANT PROTECTION AND

Plant Inspection Station
Bldg. 77, JFK International
Jamaica, NY 11430-1096

APHIS FORM 2051 (JUL 89)

PERMIT NO. 02-

See acknowledgment letter

(b)(6), (b)(7)(c)

See acknowledgment letter

(b)(6), (b)(7)(c)

Expires

See acknowledgment letter

(b)(6), (b)(7)(c)

See acknowledgment letter

(b)(6), (b)(7)(c)



OR 120018 BR 003142

See acknowledgment letter

(b)(6), (b)(7)(c)

APHIS FORM 2051 (JUL 89)

PERMIT NO. 02-

U.S. DEPARTMENT

DEL

ANIMAL AND PLANT HEALTH

PLANT PROTECTION AND

Plant Inspection Station

Bldg. 77, JFK International

Jamaica, NY 11430-1096

MONSANTO

Food - Health - Hope



Monsanto Company
700 Chesterfield Pkwy North
Chesterfield, Missouri 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

February 01, 2002

TO: **Packet Receiver(s)**
CC: **Notification Requestor**
Subject: **Import**
USDA #02-003-06n (Monsanto #2001-849XC)
Regulated article: Wheat
Country of Origin: Czech Republic **Country of Destination: USA**

Duration of Notification: February 02, 2002 through February 02, 2003

Project Identifier: RR wheat

Thank you for your participation in Monsanto's Biotechnology Research in the United States. The responsible management of research, development and use of biotechnology products is critical to the advancement and acceptance of biotechnology. This, in turn, will move us toward our vision of abundant food and a healthy environment.

This notification request for Import of regulated material has been acknowledged and may be executed on or after **February 02, 2002**. The authorization under this notification is valid until **February 02, 2003**.

In this compliance packet, please find:

1. Approvals
2. Performance Standards

Please read the entire package carefully, adhering to all requests that apply, including completion of all necessary forms. Strict compliance is very important. Therefore, it is essential that all conditions of the notification are understood and followed.

If you have any questions about the restrictions that apply to this notification, compliance packet, or compliance requirements, please contact me immediately at (b) (6), (b) (7)(C).

For technical questions regarding the regulated material covered by this notification, please contact the Monsanto researcher responsible for this project, (b) (6), (b) (7)(C) 3 (b) (6), (b) (7)(C).

We appreciate your cooperation and compliance with the regulatory requirements essential to the success of our regulatory compliance program.



OR120018_BR_003144

Sincerely,

(b) (6), (b) (7)(C)



DEPARTMENTAL PERMIT NO. 62741
(Revised)

Valid for importations made
before January 31, 2004

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway, North
St. Louis, Missouri 63198

(b) (6), (b) (7)(C) AX: (314) 737-7085

the conditions specified below

Various Countries

Various Ports of Entry Staffed by PPQ-USDA (A copy of this import permit must be
provided to each port of entry or must
accompany each

Various Prohibited Plants and/or Plant Parts for Laboratory Analysis

(b)(4)

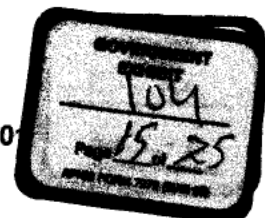
Any alteration, forgery, or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001).

/s/ Karen S. Brady /for

(b) (6), (b) (7)(C)

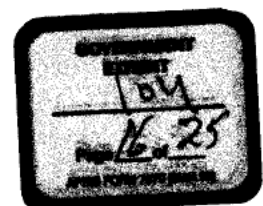
(b) (6), (b) (7)(C)

1/10/04



OR120018_BR_003147

(b)(4)



MONSANTO

Food • Health • Hope™



Compliance Packet

2002

Seed received
Nov 2002
1 import sticker used.
4 stickers returned
19 Nov 2002 JS

Importation

USDA #: 02-003-06n

Monsanto #: 2001-849XC

Effective Date: 02/02/2002

Expiration Date: 02/02/2003

Crop: Wheat

Project Identifier: RR wheat

Notification Requestor: (b) (6), (b) (7)(C)

Phone No.: (b) (6), (b) (7)(C)

GOVERNMENT
EXHIBIT

Page 17 of 25

APHIS FORM 7070 (MAR 05)

OR120018_BR_003151

(b) (6), (b) (7)(C)

From:

(b) (6), (b) (7)(C)

Sent:

Monday, July 22, 2002 11:55 AM

To:

(b) (6), (b) (7)(C)

Cc:

Subject:

RE: RH wheat

(b)(4)

-----Original Message-----

From:

(b) (6), (b) (7)(C)

Sent:

Monday, July 08, 2002 9:16 PM

To:

(b) (6), (b) (7)(C)

Cc:



(b) (6), (b) (7)(C) Received this Document From:

Bernadette Juarez, Director
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on June 04, 2013

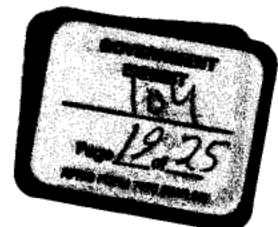
Subject: RR wheat

(b) (6), (b) (7)(C)

(b)(4)

Thanks,

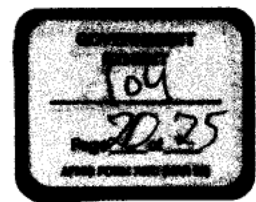
(b) (6), (b) (7)(C)



(b) (6), (b) (7)(C) Received this Document From:
Bernadette Juarez, Director
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on June 04, 2013

OR120018_BR_003155

(b)(4)



(b) (6), (b) (7)(C) Received this Document From:
Bernadette Juarez, Director
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on June 04, 2013

OR120018_BR_003157

(b)(4)



(b) (6), (b) (7)(C) Received this Document From:
Bernadette Juarez, Director
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on June 04, 2013

MONSANTO



CONFIDENTIAL

November 11, 2003

MONSANTO COMPANY
700 CHESTERFIELD PIKE NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

(b)(4)

(b)(6), (b)(7)(C)

(b)(6), (b)(7)(C) CBI



OR120018_BR_003160

MONSANTO



(b)(6), (b)(7)(c)

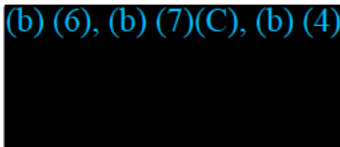


MONSANTO COMPANY
LAW DEPARTMENT
800 NORTH LINDBERGH BOULEVARD
ST. LOUIS, MISSOURI 63107
<http://www.monsanto.com>

February 13, 2004

VIA FACSIMILE 573-729-2477
& REGULAR MAIL

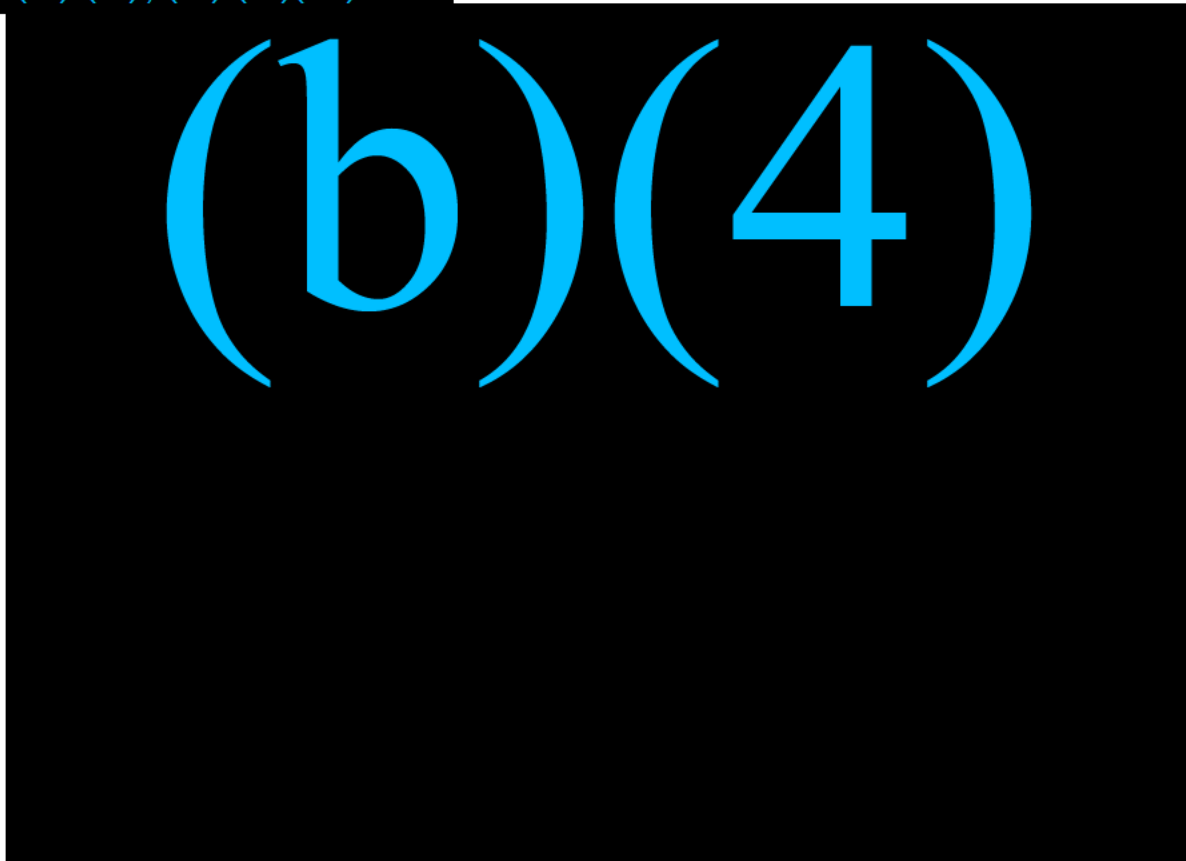
(b) (6), (b) (7)(C), (b) (4)



Re: Investigation into potentially lost wheat seeds at Monsanto St. Louis facility

(b) (6), (b) (7)(C)

(b)(4)



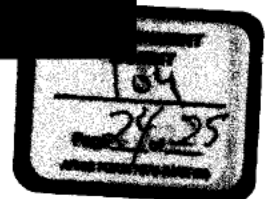
OR120018_BR_003161

2002-001-11

8 11 0007-61-70

(b) (6), (b) (7)(C) Received this Document From:
Bernadette Juarez, Director
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on June 04, 2013

(b)(4)



(b) (6), (b) (7)(C) Received this Document From:
Bernadette Juarez, Director
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on June 04, 2013

(b)(4)

Sincerely,

(b) (6), (b) (7)(C)
(b) (6), (b) (7)(C)

(b) (7)(C), (b) (6)



(b) (6), (b) (7)(C) Received this Document From:
Bernadette Juarez, Director
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on June 04, 2013



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 7, 2002

Dear Mr. Brown:

Enclosed is notification 02-003-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-003-06n	Applicant #:	2001-849XC
Received:	January 3, 2002	Effective:	February 2, 2002
Institution:	Monsanto	Recipient:	Wheat
Import destination:	MO		
Interstate destination:			
Release destination:			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

✓ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State: Missouri

Signature: (b) (6), (b) (7)(C)

Date: 1/18/02

State: MO

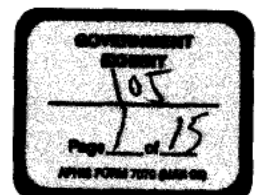
Rptloc01/R4



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_003167



(b) (6), (b) (7)(C) Received this Document From:

Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 8, 2002

Dear Mr. Brown:

Enclosed is notification 02-003-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	02-003-06n	Applicant #:	2001-849XC
Received:	January 3, 2002	Effective:	February 2, 2002
Institution:	Monsanto	Recipient:	Wheat
Import destination:	MO		
Interstate destination:			
Release destination:			

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

|S|

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

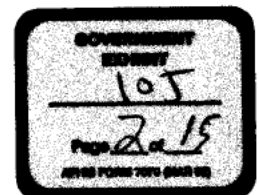
Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4



OR120018_BR_003169

(b) (6), (b) (7)(C) Received this Document From:
Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

OR120018_BR_003170

January 31, 2002

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway N.
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after February 2, 2002.

Import

Notification no. 02-003-06n (2001-849XC)
Regulated article - Wheat
Destination - Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

See the attached information on importation.

In addition, you must obtain a departmental permit. For more information, please contact Ms. Karen Brady at (301) 734-5208.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official.

Sincerely,

|S|

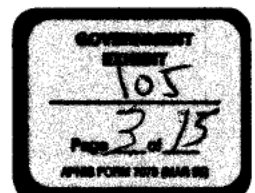
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessment
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
OIC, J.F.K.I.A, Jamaica, NY
File number 02-003-06n

OR120018_BR_003171



(b) (6), (b) (7)(C) Received this Document From:
Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

MONSANTO



NO CBI

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

2/25/2003

Ms. Kimberly Diggs
Animal and Plant Inspection Services
Biotechnology, Biologics, and Environmental Protection
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737-1236

Reference: Return of unused Importation Labels

Dear Ms. Diggs,

As required for USDA import notifications, enclosed are the unused importation labels from the following USDA notifications that have expired:

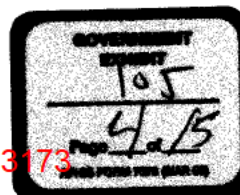
<u>USDA #</u>	<u>Monsanto ID#</u>	<u>Expiration date</u>	<u>Crop</u>	<u># Received</u>	<u># Returned</u>
01-247-01n	2001-616XC	10/23/2002	Corn	365	29
01-299-04n	2001-719XC	11/25/2002	Cotton	5	5
01-341-07n	2001-765XC	01/06/2003	Rice	5	4
01-341-08n	2001-766XC	01/06/2003	Rice	5	4
02-003-06n	2001-849XC	02/02/2003	Wheat	5	4

If you require any further information, please call me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

Phone: (b) (6), (b) (7)(C)
Fax: 636/737-7085



SEP 13 2004

OR120018_BR_003173

(b) (6), (b) (7)(C) Received this Document From:
Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2001-849XC

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

02-003-06n

1. USDA Reference Number

2. Applicant Reference Number 2001-849XC

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO

63198

Phone
FAX
EMail

(b) (6), (b) (7)(C)

636/737-7085

(b) (6), (b) (7)(C)

4. Duration of Introduction

Import

February 01, 2002 - February 01, 2003

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

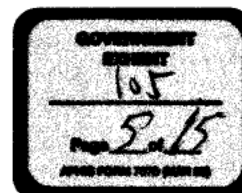
Phenotypic Category:

HT

Phenotype:

Glyphosate tolerant

Bobwhite



(b) (6), (b) (7)(C) Received this Document From:
Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

Monsanto Reference ID

2001-849XC

designation of transformed line:

33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMeVa/12

(b)(4)

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMeP3/15

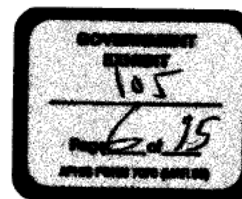
(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



(b) (6), (b) (7)(C) Received this Document From:
Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

OR120018_BR_003178

Monsanto Reference ID
2001-849XC

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Import

. Ship up to ____20____ pounds wheat seed to and from each location.

ORIGIN:
Czech Republic

DESTINATION:
USA

Ship From:

CR

(b)(4) Branisovice County/Province, CR,
CR, Czech Republic

CONTACT: (b)(6), (b)(7)(C), (b)(4) CR,
CR, Czech

] - CBI

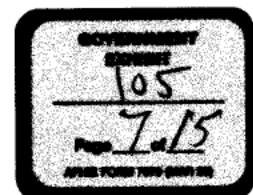
Ship To:

MO

(b)(4) St. Louis County/Province, MO, (b)(4)
USA

CONTACT: (b)(6), (b)(7)(C), (b)(4) MO,
(b)(6), (b)(7)(C), (b)(4) USA,

] - CBI



(b) (6), (b) (7)(C) Received this Document From:
Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

MONSANTO



MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

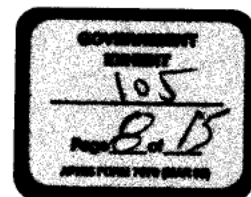
Monsanto Reference ID
2001-849XC

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company



(b) (6), (b) (7)(C) Received this Document From:
Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

OR120018_BR_003182

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

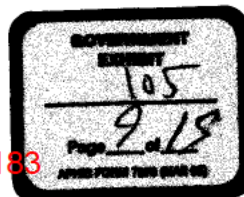
The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C. Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C. Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purpose of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C. Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below*.



(b) (6), (b) (7)(C) Received this Document From:
Natalie Popovic, Branch Chief
Plant Health and Border Protection Enforcement Branch
Investigative and Enforcement Services
USDA APHIS MRPBS
(via e-mail) on December 04, 2013

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.



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Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



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MONSANTO



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Monsanto Reference ID
2001-849XC

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

02-003-06n

1. **USDA Reference Number**
2. **Applicant Reference Number** 2001-849XC
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO

63198

Phone
FAX
EMail

(b) (6), (b) (7)(C)

636/737-7085

(b) (6), (b) (7)(C)

4. **Duration of Introduction**
Import

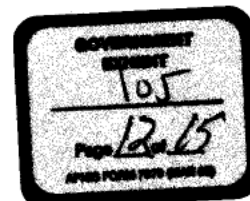
February 01, 2002 - February 01, 2003

5. **Recipient**
Wheat, Triticum aestivum

6. **Regulated Article**

Phenotypic Category: HT
Phenotype: Glyphosate tolerant

Bobwhite



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Monsanto Reference ID

2001-849XC

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

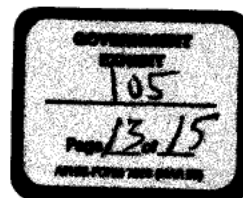
GENE OF INTEREST

Promoter: CMP3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



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OR120018_BR_003192

Monsanto Reference ID

2001-849XC

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Import

Ship up to ___20___ pounds wheat seed to and from each location.

ORIGIN:

Czech Republic

DESTINATION:

USA

Ship From:

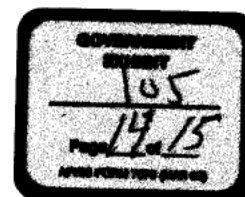
CR

[CBI Deleted] -- *Branisovice County/Province, CR, Czech Republic

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA



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FAX (636) 737-7085
<http://www.monsanto.com>

Monsanto Reference ID
2001-849XC

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

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Monsanto Company



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US006689880B2

(12) **United States Patent**
Chen et al.

(10) **Patent No.:** **US 6,689,880 B2**
(45) Date of Patent: **Feb. 10, 2004**

(54) **DNA MOLECULE FOR DETECTING
 GLYPHOSATE TOLERANT WHEAT PLANT
 33391 AND PROGENY THEREOF**

5,948,956 A 9/1999 Lee et al. 800/320

(75) **Inventors:** **Guilan Chen**, Chesterfield, MO (US);
Catherine M. Hironaka, Dublin, CA
 (US); **Hua-ping Zhou**, Chesterfield,
 MO (US)

EP 1 167 531 A 1/2002
 WO WO 99 46396 A 9/1999

FOREIGN PATENT DOCUMENTS

(73) **Assignee:** **Monsanto Technology LLC**, St. Louis,
 MO (US)

(*) **Notice:** Subject to any disclaimer, the term of this
 patent is extended or adjusted under 35
 U.S.C. 154(b) by 96 days.

OTHER PUBLICATIONS

(21) **Appl. No.:** **09/682,597**

(22) **Filed:** **Sep. 25, 2001**

(65) **Prior Publication Data**

US 2002/0062503 A1 May 23, 2002

Related U.S. Application Data

(60) Provisional application No. 60/236,762, filed on Sep. 29,
 2000, and provisional application No. 60/236,653, filed on
 Sep. 29, 2000.

(51) **Int. Cl.⁷** **C12N 15/29**; C12N 15/82;
 C12N 15/84

(52) **U.S. Cl.** **536/24.3**; 536/23.1; 536/23.2;
 800/300; 800/320.2; 435/320.1

(58) **Field of Search** 536/23.1, 23.2,
 536/24.3; 800/300, 320.2; 435/320.1

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,633,435 A 5/1997 Barry et al. 800/288

Zhou, H et al, "Glyphosphate tolerant CP4 and GOX genes
 as a selectable marker in wheat transformation," Plant Cell
 Reports, Springer Verlag (DE), vol. 15 (No. 3/4), p.
 159-163, (Dec. 1, 1995).

Windels, P et al, "Development of a line specific GMO
 detection method a case study," Mededelingen Van De
 Faculteit, Landbouwwetenschappen Universiteit Gent (BE),
 vol. 64 (No. 5B), p. 459-462, (Sep. 22, 1999).

Saroha, M K et al, "Glyphosate tolerant crops: genes and
 enzymes," J Plant Biochem and Biotech, Society for Plant
 Biochemistry and Biotechnology (IN), p. 65-72, (Jul. 7,
 1998).

Primary Examiner—David T. Fox

Assistant Examiner—David H Kruse

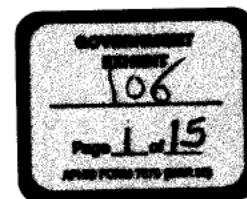
(74) *Attorney, Agent, or Firm*—E. Clifford Lawson;
 Thomas P. McBride

(57) **ABSTRACT**

The present invention provides a DNA construct composi-
 tion that relates to transgenic glyphosate tolerant wheat
 plants. The invention relates to the wheat plant 33391, the
 progeny thereof and to methods for the detection of wheat
 plant 33391 and its progeny and compositions thereof.

1 Claim, 3 Drawing Sheets

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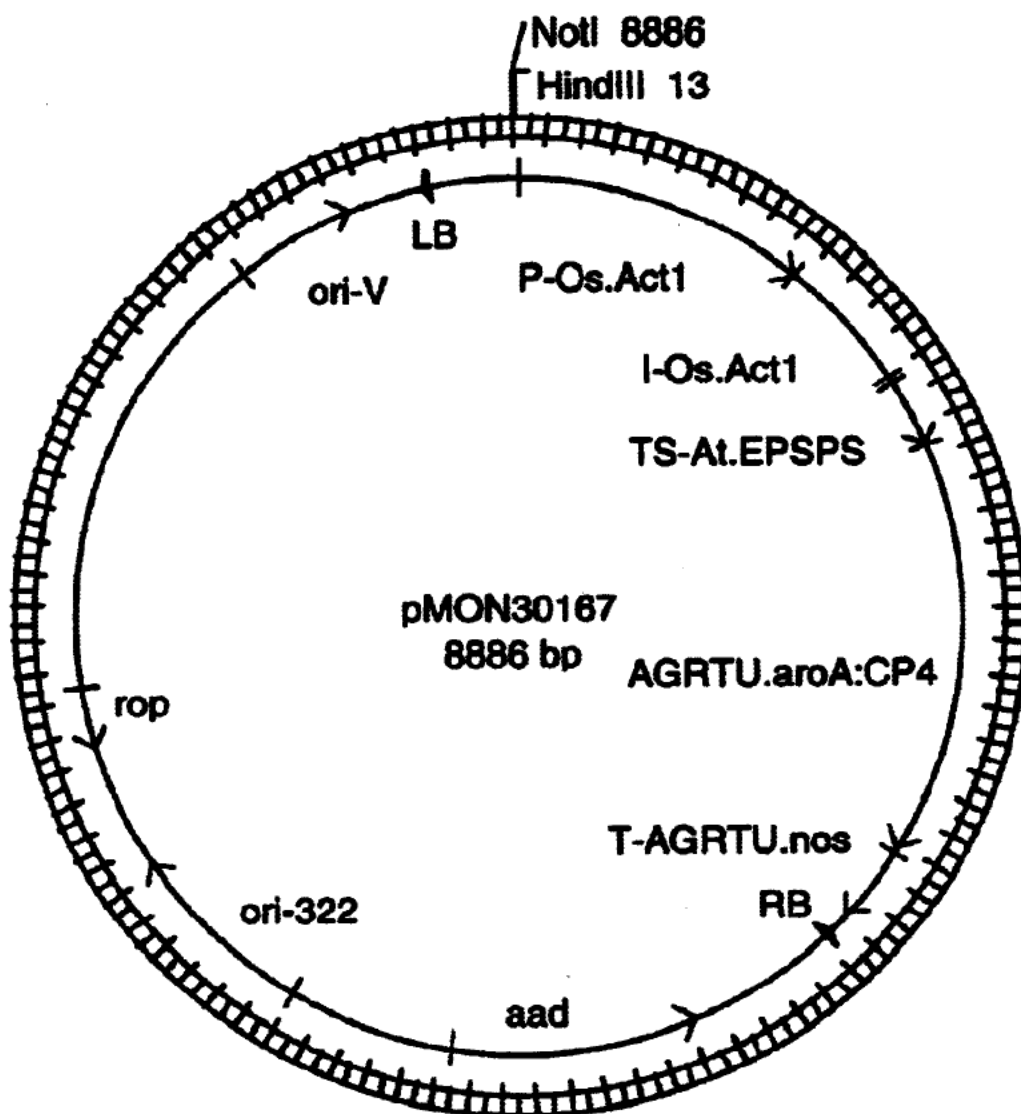


Figure 1

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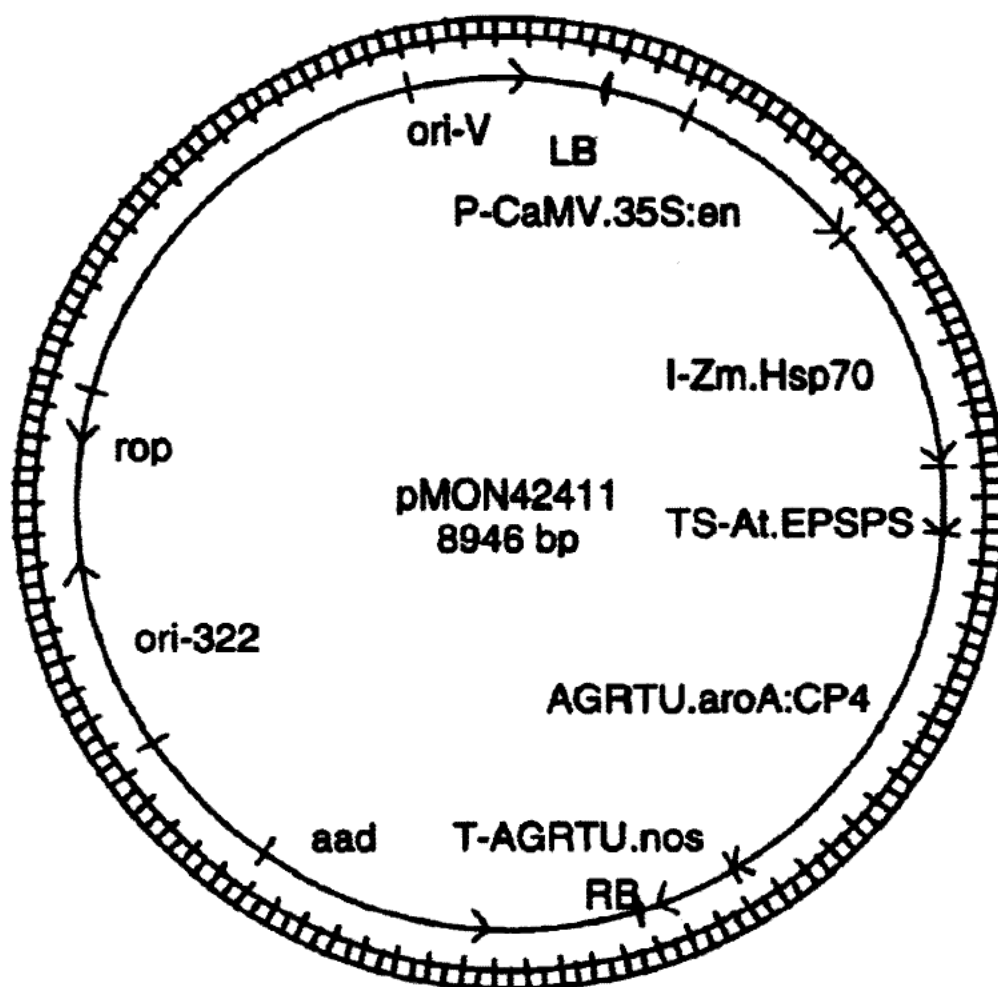


Figure 2

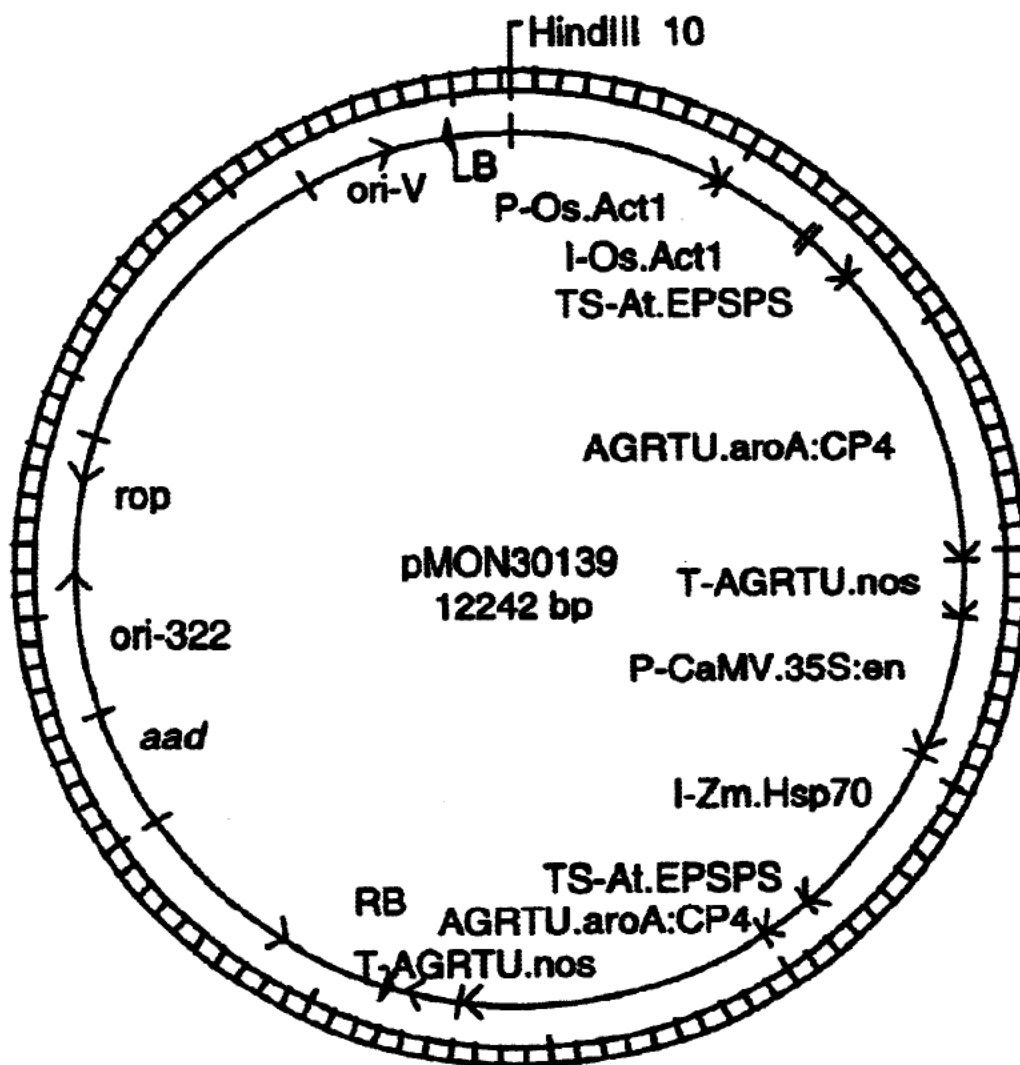


Figure 3

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1

DNA MOLECULE FOR DETECTING GLYPHOSATE TOLERANT WHEAT PLANT 33391 AND PROGENY THEREOF

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/236,762, filed Sep. 29, 2000 and U.S. Provisional Application No. 60/236,653 filed Sep. 29, 2000.

BACKGROUND OF INVENTION

The present invention relates to the field of plant molecular biology, more specifically the invention relates to a DNA construct for conferring improved glyphosate tolerance to a wheat plant. The invention more specifically relates to a glyphosate tolerant wheat plant 33391 and progeny thereof and to assays for detecting the presence of wheat plant 33391 DNA in a sample and compositions thereof.

Wheat is an important crop and is a primary food source in many areas of the world. The methods of biotechnology have been applied to wheat for improvement of the agronomic traits and the quality of the product. One such agronomic trait is herbicide tolerance, in particular, tolerance to glyphosate herbicide. This trait in wheat is conferred by the expression of a transgene in the wheat plants (Zhou et al., Plant Cell Rep. 15:159-163, 1995). The expression of foreign genes in plants is known to be influenced by their chromosomal position, perhaps due to chromatin structure (e.g., heterochromatin) or the proximity of transcriptional regulation elements (e.g., enhancers) close to the integration site (Weising et al., Ann. Rev. Genet. 22:421-477, 1988). For this reason, it is often necessary to screen a large number of events in order to identify an event characterized by optimal expression of a introduced gene of interest. For example, it has been observed in plants and in other organisms that there may be a wide variation in levels of expression of an introduced gene among events. There may also be differences in spatial or temporal patterns of expression, for example, differences in the relative expression of a transgene in various plant tissues, that may not correspond to the patterns expected from transcriptional regulatory elements present in the introduced gene construct. For this reason, it is common to produce hundreds to thousands of different events and screen those events for a single event that has desired transgene expression levels and patterns for commercial purposes. An event that has desired levels or patterns of transgene expression is useful for introgressing the transgene into other genetic backgrounds by sexual outcrossing using conventional breeding methods. Progeny of such crosses maintain the transgene expression characteristics of the original transformant. This strategy is used to ensure reliable gene expression in a number of varieties that are well adapted to local growing conditions.

It would be advantageous to be able to detect the presence of a particular event in order to determine whether progeny of a sexual cross contain a transgene of interest. In addition, a method for detecting a particular event would be helpful for complying with regulations requiring the premarket approval and labeling of foods derived from recombinant crop plants, for example. It is possible to detect the presence of a transgene by any well known nucleic acid detection method such as the polymerase chain reaction (PCR) or DNA hybridization using nucleic acid probes. These detection methods generally focus on frequently used genetic elements, such as promoters, terminators, marker genes, etc. As a result, such methods may not be useful for discrimi-

2

nating between different events, particularly those produced using the same DNA construct unless the sequence of chromosomal DNA adjacent to the inserted DNA ("flanking DNA") is known. An event-specific PCR assay is discussed, for example, by Windels et al. (Med. Fac. Landbouww, Univ. Gent 64/5b:459-462, 1999), who identified glyphosate tolerant soybean event 40-3-2 by PCR using a primer set spanning the junction between the insert and flanking DNA, specifically one primer that included sequence from the insert and a second primer that included sequence from flanking DNA.

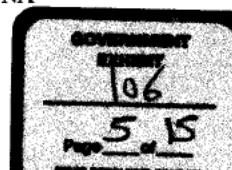
This invention relates to the improved glyphosate herbicide tolerant wheat (*Triticum aestivum*) plant 33391 and to a DNA plant expression construct of wheat plant 33391 and the detection of the transgene/genomic insertion region in wheat 33391 and progeny thereof.

SUMMARY OF INVENTION

According to one aspect of the invention, a DNA construct is provided that when expressed in wheat plant cells and wheat plants confers improved tolerance to glyphosate herbicide. This invention relates to the methods for producing and selecting a glyphosate tolerant wheat plant containing the DNA construct pMON30139. The DNA construct, pMON30139 consists of two transgene expression cassettes. The first expression cassette consists of a rice (*Oryza sativa*) actin 1 promoter (P-Os.Act1) and intron (I-Os.Act1) operably joined to an Arabidopsis EPSPS chloroplast transit peptide sequence (TS-At.EPSPS), operably connected to a gene (AGRTU.aroA:CP4) encoding a glyphosate resistant 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) isolated from *Agrobacterium tumefaciens* (AGRTU) sp. strain CP4, operably connected to a nopaline synthase transcriptional terminator (T-AGRTU.nos). The second transgene expression cassette consists of the cauliflower mosaic virus (CaMV) 35S promoter (P-CaMV.35S:en) containing a tandem duplication of the enhancer region, operably connected to a *Zea mays* Hsp70 intron (I-Zm.Hsp70), operably connected to a nucleic acid sequence encoding an *Arabidopsis thaliana* EPSPS chloroplast transit peptide sequence, operably connected to a gene encoding a glyphosate resistant 5-enol-pyruvylshikimate-3-phosphate synthase isolated from *Agrobacterium tumefaciens* sp. strain CP4, operably connected to a nopaline synthase transcriptional terminator. These expression cassettes are in tandem and flanked by DNA regions that contain *Agrobacterium tumefaciens* DNA sequences (RB and LB) as a components of the process that is used in an *Agrobacterium* mediated method to insert of the expression cassettes into a wheat genome.

According to another aspect of the invention, wheat 33391 seed comprising such DNA molecules are provided as deposited with the ATCC, accession # PTA-2347. This aspect of the invention thus relates to the seeds of wheat 33391, to the plants of wheat 33391, to the plant parts of wheat 33391 that includes pollen and ovules, and to the methods for producing an improved glyphosate tolerant wheat plant by crossing the wheat plant 33391 with itself or another wheat plant.

According to another aspect of the invention, compositions and methods are provided for detecting the presence of the transgene/genomic insertion region from wheat 33391 plants and seeds. According to one aspect of the invention, DNA molecules are provided that comprise at least one transgene/genomic insertion region sequence of wheat 33391 selected from the group consisting of SEQ ID NO:5 and SEQ ID NO:6 and complements thereof, wherein an insertion region sequence spans the junction between heterologous DNA inserted into the wheat genome and DNA



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from the wheat genome flanking the insertion site and is diagnostic for the event. Included are DNA sequences that comprise a sufficient length of polynucleotides of transgene insert sequence and a sufficient length of polynucleotides of wheat genomic sequence from wheat 33391 of SEQ ID NO:5 that are useful as primer sequences for the production of an amplicon product diagnostic for wheat 33391. Included are DNA sequences that comprise a sufficient length of polynucleotides of transgene insert sequence and a sufficient length of polynucleotides of wheat genomic sequence from wheat 33391 of SEQ ID NO:6 that are useful as primer sequences for the production of an amplicon product diagnostic for wheat 33391.

According to another aspect of the invention DNA molecules are provided that are diagnostic for wheat 33391. This aspect of the invention is directed to the wheat 33391 containing at least one novel DNA molecule. DNA molecules comprising nucleic acid primers are provided that provide at least one novel DNA amplicon product of wheat 33391 consisting of SEQ ID NO:7 and SEQ ID NO:8, or the complements thereof. Such DNA amplicons are diagnostic for wheat 33391. Nucleic acid amplification of genomic DNA of the wheat 33391 produces an amplicon comprising such diagnostic DNA sequences. The invention provides isolated DNA molecules that comprise a sufficient length of transgene insert sequence and a sufficient length of wheat genomic sequence from wheat 33391 to function as primer sequences for the production of an amplicon product diagnostic for wheat 33391.

According to another aspect of the invention, methods of detecting the presence of DNA corresponding to the wheat 33391 in a sample are provided. Such methods comprise: (a) contacting the sample comprising DNA with a primer set that, when used in a nucleic-acid amplification reaction with genomic DNA from wheat 33391, produces an amplicon that is diagnostic for wheat 33391; (b) performing a nucleic acid amplification reaction, thereby producing the amplicon; and (c) detecting the amplicon.

According to another aspect of the invention, a kit is provided for the detection of wheat 33391. The kit includes at least one DNA sequence of sufficient length of polynucleotides complementary to SEQ ID NO:5 or SEQ ID NO:6, wherein the DNA sequences are useful as primers or probes that hybridize to isolated DNA from wheat 33391 or its progeny.

According to another aspect of the invention, methods of producing a wheat plant with improved tolerance to glyphosate are provided that comprise the steps of: (a) sexually crossing a first parental wheat line comprising the pMON30139 construct that confers improved tolerance to application of glyphosate, and a second parental wheat line that lacks glyphosate tolerance, thereby producing a plurality of progeny plants; and (b) selecting a progeny plant that tolerates application of glyphosate. Such methods are useful for introgressing the glyphosate tolerant trait into different genetic backgrounds. Such methods may optionally comprise the further step of back-crossing the progeny plant to the second parental wheat line to produce a wheat plant that tolerates application of glyphosate.

The foregoing and other aspects of the invention will become more apparent from the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1. Plasmid map of pMON30167

FIG. 2. Plasmid map of pMON42411

FIG. 3. Plasmid map of pMON30139

DETAILED DESCRIPTION

This application claims the benefit of U.S. Provisional Application No. 60/236,762, filed Sep. 29, 2000 and U.S.

Provisional Application No. 60/236,653 filed Sep. 29, 2000. The following definitions and methods are provided to better define the present invention and to guide those of ordinary skill in the art in the practice of the present invention. Unless otherwise noted, terms are to be understood according to conventional usage by those of ordinary skill in the relevant art. Definitions of common terms in molecular biology may also be found in Rieger et al., *Glossary of Genetics: Classical and Molecular*, 5th edition, Springer-Verlag: New York, 1991; and Lewin, *Genes V*, Oxford University Press: New York, 1994. The nomenclature for DNA bases as set forth at 37 CFR §1.822 is used.

As used herein, the term "wheat" means *Triticum aestivum* (including spring, winter, and facultative wheat varieties) any other wheat species that can be bred with *Triticum aestivum*, including but not limited to durum wheat (*Triticum durum*), spelt (*Triticum spelta*), and emmer (*Triticum dicoccum*). Also encompassed are plants that are produced by conventional techniques using *Triticum aestivum* as a parent in a sexual cross with a non-Triticum species (such as rye [*Secale cereale*]), including but not limited to triticale.

As used herein, the term "comprising" means "including but not limited to".

"Glyphosate" refers to N-phosphonomethylglycine and its salts. Glyphosate is the active ingredient of Roundup® herbicide (Monsanto Co, St. Louis, Mo.). Treatments with "glyphosate herbicide" refer to treatments with the Roundup®, Roundup Ultra® herbicide or any other formulation containing glyphosate. For the purposes of the present invention, the term "glyphosate" includes any herbicidally active form of N-phosphonomethylglycine (including any salt thereof) and other forms that result in the production of the glyphosate anion in plants. Treatments with "glyphosate" refer to treatments with the Roundup® or Roundup Ultra® herbicide formulation, unless otherwise stated. Plant transformation and regeneration in tissue culture use glyphosate or salts of glyphosate. Whole plant assays use formulated Roundup® or Roundup Ultra®. Additional formulations with herbicide activity that contain N-phosphonomethylglycine or any of its salts are herein included as a glyphosate herbicide.

A transgenic "event" is produced by transformation of plant cells with heterologous DNA, i.e., a nucleic acid construct that includes a transgene of interest, regeneration of a population of plants resulting from the insertion of the transgene into the genome of the plant, and selection of a particular plant characterized by insertion into a particular genome location. The term "event" refers to the original transformant and progeny of the transformant that include the heterologous DNA. The term "event" also refers to progeny produced by a sexual outcross between the transformant and another variety that include the heterologous DNA. Even after repeated back-crossing to a recurrent parent, the inserted DNA and flanking DNA from the transformed parent is present in the progeny of the cross at the same chromosomal location. The term "event" also refers to DNA from the original transformant and progeny thereof comprising the inserted DNA and flanking genomic sequence immediately adjacent to the inserted DNA that would be expected to be transferred to a progeny that receives inserted DNA including the transgene of interest as the result of a sexual cross of one parental line that includes the inserted DNA (e.g., the original transformant and progeny resulting from selfing) and a parental line that does not contain the inserted DNA. The "event" of the present invention comprises wheat 33391 seed having ATCC acces-

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sion No. PTA-2347 and wheat plants grown from the wheat 33391 and progeny thereof. A wheat plant that tolerates a sufficient amount of glyphosate herbicide to control the weeds in a field without affecting the wheat plant can be bred by first sexually crossing a first parental wheat plant consisting of a wheat plant containing the expression cassettes of pMON30139 that confers improved tolerance to application of glyphosate herbicide, and a second parental wheat plant that lacks the tolerance to glyphosate herbicide, thereby producing a plurality of first progeny plants; and then selecting a first progeny plant that is tolerant to application of glyphosate herbicide; and selfing the first progeny plant, thereby producing a plurality of second progeny plants; and then selecting from the second progeny plants a glyphosate herbicide tolerant plant. These steps can further include the back-crossing of the first glyphosate tolerant progeny plant or the second glyphosate tolerant progeny plant to the second parental wheat plant or a third parental wheat plant, thereby producing a wheat plant that tolerates the application of glyphosate herbicide. A wheat crop comprising wheat 33391 seeds or progeny thereof can be planted in a field and treated with a sufficient amount of glyphosate herbicide to control the weeds without significantly affecting the wheat crop. A sufficient amount of glyphosate herbicide is about 8 ounces/acre or more, 16 ounces/acre or more, 32 ounces/acre or more, or 64 ounces/acre or more. Any glyphosate containing herbicide formulation can be used to control weeds in a wheat crop comprising wheat 33391 plants or progeny thereof.

It is also to be understood that two different transgenic plants can also be mated to produce offspring that contain two independently segregating added, exogenous genes. Selfing of appropriate progeny can produce plants that are homozygous for both added, exogenous genes that encode a polypeptide of interest. Back-crossing to a parental plant and out-crossing with a non-transgenic plant are also contemplated, as is vegetative propagation. Descriptions of other breeding methods that are commonly used for different traits and crops can be found in one of several references, e.g., Fehr, in *Breeding Methods for Cultivar Development*, Wilcox J. ed., American Society of Agronomy, Madison Wis. (1987) herein incorporated by reference in its entirety; Poehlman, J. M. (1987); *Breeding Field Crops*, 3rd ed. Van Nostrand Reinhold, N.Y., Knott, D. R. (1987); herein incorporated by reference in its entirety. The Application of Breeding Procedures to Wheat, p. 419-427. In E. G. Heyne (ed.) In "Wheat and Wheat Improvement", Madison, Wis. herein incorporated by reference in its entirety. Backcross breeding has been used to transfer genes for a simply inherited, highly heritable trait into a desirable homozygous cultivar or inbred line, which is the recurrent parent. The source of the trait to be transferred is called the donor parent. The resulting plant is expected to have the attributes of the recurrent parent (e.g., cultivar) and the desirable trait transferred from the donor parent. After the initial cross, individuals possessing the phenotype of the donor parent are selected and repeatedly crossed (backcrossed) to the recurrent parent. The resulting parent is expected to have the attributes of the recurrent parent (e.g., cultivar) and the desirable trait transferred from the donor parent.

The DNA molecules of the present invention can be used as molecular markers in a marker assisted breeding (MAB) method. DNA molecules of the present invention can be used in methods, such as, AFLP markers, RFLP markers, RAPD markers, SNPs, and SSRs that identify genetically linked agronomically useful traits as described by Walton, *Seed World* 22-29 (July, 1993), the entirety of which is

herein incorporated by reference; Burow and Blake, *Molecular Dissection of Complex Traits*, 13-29, Eds. Paterson, CRC Press, New York (1988), the entirety of which is herein incorporated by reference). The improved glyphosate tolerance trait of wheat plant 33391 can be tracked in the progeny of a cross with wheat plant 33391 and any other wheat cultivar or variety using the MAB methods. The DNA molecules are markers for this trait and in MAB methods that are well known in the art can be used to track glyphosate tolerance in wheat where wheat plant 33391 was a parent or ancestor.

A "probe" is an isolated nucleic acid to which is attached a conventional detectable label or reporter molecule, e.g., a radioactive isotope, ligand, chemiluminescent agent, or enzyme. Such a probe is complementary to a strand of a target nucleic acid, in the case of the present invention, to a strand of genomic DNA from wheat event 33391 (whether from a wheat plant or from a sample that includes DNA from the event). Probes according to the present invention include not only deoxyribonucleic or ribonucleic acids but also polyamides and other probe materials that bind specifically to a target DNA sequence and can be used to detect the presence of that target DNA sequence.

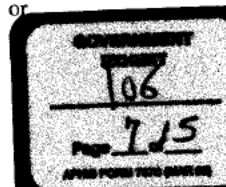
"Primers" are isolated nucleic acids that are annealed to a complementary target DNA strand by nucleic acid hybridization to form a hybrid between the primer and the target DNA strand, then extended along the target DNA strand by a polymerase, e.g., a DNA polymerase. Primer pairs or sets can be used for amplification of a nucleic acid sequence, e.g., by the polymerase chain reaction (PCR) or other conventional nucleic-acid amplification methods.

Probes and primers are generally 8 polynucleotides or more in length, 18 polynucleotides or more, 24 polynucleotides or more, 30 polynucleotides or more. Polynucleotides useful as probes and primers that are of sufficient length to hybridize specifically to a target sequence under stringent conditions for hybridization. Probes and primers according to the present invention have complete sequence similarity with the target sequence, although probes differing from the target sequence and that retain the ability to hybridize to target sequences may be designed by conventional methods.

Methods for preparing and using probes and primers are described, for example, in *Molecular Cloning: A Laboratory Manual*, 2nd ed., vol. 1-3, ed. Sambrook et al., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., 1989 (hereinafter, "Sambrook et al., 1989") herein incorporated by reference in its entirety; *Current Protocols in Molecular Biology*, ed. Ausubel et al., Greene Publishing and Wiley-Interscience, New York, 1992 (with periodic updates) (hereinafter, "Ausubel et al., 1992") herein incorporated by reference in its entirety; and Innis et al., *PCR Protocols: A Guide to Methods and Applications*, Academic Press: San Diego, 1990 herein incorporated by reference in its entirety. PCR-primer pairs can be derived from a known sequence, for example, by using computer programs intended for that purpose such as Primer (Version 0.5, © 1991, Whitehead Institute for Biomedical Research, Cambridge, Mass.) herein incorporated by reference in its entirety.

Primers and probes based on the flanking DNA and insert sequences disclosed herein can be used to confirm (and, if necessary, to correct) the disclosed sequences by conventional methods, e.g., by re-cloning and sequencing such sequences.

The nucleic-acid probes and primers of the present invention hybridize under stringent conditions to a target DNA sequence. Any conventional nucleic acid hybridization or



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amplification method can be used to identify the presence of DNA from a transgenic event in a sample.

The term "stringent conditions" is functionally defined with regard to the hybridization of a nucleic-acid probe to a target nucleic acid (i.e., to a particular nucleic-acid sequence of interest) by the specific hybridization procedure discussed in Sambrook et al., 1989, at 9.52-9.55. See also, Sambrook et al., 1989 at 9.47-9.52, 9.56-9.58 herein incorporated by reference in its entirety; Kanehisa, (Nucl. Acids Res. 12:203-213, 1984, herein incorporated by reference in its entirety); and Wetmur and Davidson, (J. Mol. Biol. 31:349-370, 1988, herein incorporated by reference in its entirety). Accordingly, the nucleotide sequences of the invention may be used for their ability to selectively form duplex molecules with complementary stretches of DNA fragments. Depending on the application envisioned, one will desire to employ varying conditions of hybridization to achieve varying degrees of selectivity of probe towards target sequence. For applications requiring high selectivity, one will typically desire to employ relatively stringent conditions to form the hybrids, e.g., one will select relatively low salt and/or high temperature conditions, such as provided by about 0.02 M to about 0.15 M NaCl at temperatures of about 50° C. to about 70° C. A stringent conditions, for example, is to wash the hybridization filter at least twice with high-stringency wash buffer (0.2xSSC, 0.1% SDS, 65° C.). Appropriate stringency conditions which promote DNA hybridization, for example, 6.0x sodium chloride/sodium citrate (SSC) at about 45° C., followed by a wash of 2.0xSSC at 50° C., are known to those skilled in the art or can be found in Current Protocols in Molecular Biology, John Wiley & Sons, N.Y. (1989), 6.3.1-6.3.6. For example, the salt concentration in the wash step can be selected from a low stringency of about 2.0xSSC at 50° C. to a high stringency of about 0.2xSSC at 50° C. In addition, the temperature in the wash step can be increased from low stringency conditions at room temperature, about 22° C., to high stringency conditions at about 65° C. Both temperature and salt may be varied, or either the temperature or the salt concentration may be held constant while the other variable is changed. Such selective conditions tolerate little, if any, mismatch between the probe and the template or target strand. Detection of DNA sequences via hybridization is well-known to those of skill in the art, and the teachings of U.S. Pat. Nos. 4,965,188 and 5,176,995 are exemplary of the methods of hybridization analyses.

Regarding the amplification of a target nucleic-acid sequence (e.g., by PCR) using a particular amplification primer pair, "stringent conditions" are conditions that permit the primer pair to hybridize only to the target nucleic-acid sequence to which a primer having the corresponding wild-type sequence (or its complement) would bind and preferably to produce a unique amplification product, the amplicon.

The term "specific for (a target sequence)" indicates that a probe or primer hybridizes under stringent hybridization conditions only to the target sequence in a sample comprising the target sequence.

As used herein, "amplified DNA" or "amplicon" refers to the product of nucleic acid amplification of a target nucleic acid sequence that is part of a nucleic acid template. For example, to determine whether the wheat plant resulting from a sexual cross contains an transgenic event, genomic DNA from a wheat plant may be subjected to nucleic acid amplification using a primer pair that includes a primer derived from flanking sequence in the genome of the plant adjacent to the insertion site of inserted heterologous DNA

and a second primer derived from the inserted heterologous DNA to produce an amplicon that is diagnostic for the presence of the event. The amplicon is of a length and has a sequence that is diagnostic for the event. Alternatively, a primer pair can be derived from flanking sequence on both sides of the inserted DNA so as to produce an amplicon that includes the entire insert.

Nucleic acid amplification can be accomplished by any of the various nucleic acid amplification methods known in the art, including the polymerase chain reaction (PCR). A variety of amplification methods are known in the art and are described, inter alia, in U.S. Pat. Nos. 4,683,195 and 4,683,202 and in *PCR Protocols: A Guide to Methods and Applications*, ed. Innis et al., Academic Press, San Diego, 1990. Any well known method for nucleic acid amplification may be used in the practice of the present invention. The sequence of the heterologous DNA insert or flanking sequence from wheat 33391 event, ATCC accession No. PTA-2347 can be verified (and corrected if necessary) by amplifying such sequences from the event using primers derived from the sequences provided herein followed by standard methods of DNA sequencing of the PCR amplicon or of the cloned DNA molecule.

The amplicon produced by these methods may be detected by a plurality of techniques. Agarose gel electrophoresis and staining with ethidium bromide is a common well known method of detecting DNA amplicons. Another method is Genetic Bit Analysis (Nikiforov, et al. Nucleic Acid Res. 22:4167-4175, 1994) where an DNA oligonucleotide is designed which overlaps both the adjacent flanking genomic DNA sequence and the inserted DNA sequence. The oligonucleotide is immobilized in wells of a microtiter plate. Following PCR of the region of interest (using one primer in the inserted sequence and one in the adjacent flanking genomic sequence), a single-stranded PCR product can be hybridized to the immobilized oligonucleotide and serve as a template for a single base extension reaction using a DNA polymerase and labelled ddNTPs specific for the expected next base. Readout may be fluorescent or ELISA-based. A signal indicates presence of the insert/flanking sequence due to successful amplification, hybridization, and single base extension.

An additional method is the Pyrosequencing technique as described by Winge (Innov. Pharma. Tech. 00:18-24, 2000). In this method an oligonucleotide is designed that overlaps the adjacent genomic DNA and insert DNA junction. The oligonucleotide is hybridized to single-stranded PCR product from the region of interest (one primer in the inserted sequence and one in the flanking genomic sequence) and incubated in the presence of a DNA polymerase, ATP, sulfurylase, luciferase, apyrase, adenosine 5' phosphosulfate and luciferin. dNTPs are added individually and the incorporation results in a light signal which is measured. A light signal indicates the presence of the transgene/flanking sequence due to successful amplification, hybridization, and single or multi-base extension.

Fluorescence Polarization as described by Chen, et al., (Genome Res. 9:492-498, 1999) is a method that can be used to detect the amplicon of the present invention. Using this method an oligonucleotide is designed which overlaps the genomic flanking and inserted DNA junction. The oligonucleotide is hybridized to single-stranded PCR product from the region of interest (one primer in the inserted DNA and one in the flanking genomic DNA sequence) and incubated in the presence of a DNA polymerase and a fluorescent-labeled ddNTP. Single base extension results in incorporation of the ddNTP. Incorporation can be measured

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as a change in polarization using a fluorometer. A change in polarization indicates the presence of the transgene/flanking sequence due to successful amplification, hybridization, and single base extension.

Taqman® (PE Applied Biosystems, Foster City, Calif.) is described as a method of detecting and quantifying the presence of a DNA sequence and is fully understood in the instructions provided by the manufacturer. Briefly, a FRET oligonucleotide probe is designed which overlaps the genomic flanking and insert DNA junction. The FRET probe and PCR primers (one primer in the insert DNA sequence and one in the flanking genomic sequence) are cycled in the presence of a thermostable polymerase and dNTPs. Hybridization of the FRET probe results in cleavage and release of the fluorescent moiety away from the quenching moiety on the FRET probe. A fluorescent signal indicates the presence of the flanking/transgene sequence due to successful amplification and hybridization.

Molecular Beacons have been described for use in sequence detection as in Tyangi et al. (Nature Biotech. 14:303-308, 1996) Briefly, a FRET oligonucleotide probe is designed that overlaps the flanking genomic and insert DNA junction. The unique structure of the FRET probe results in it containing secondary structure that keeps the fluorescent and quenching moieties in close proximity. The FRET probe and PCR primers (one primer in the insert DNA sequence and one in the flanking genomic sequence) are cycled in the presence of a thermostable polymerase and dNTPs. Following successful PCR amplification, hybridization of the FRET probe to the target sequence results in the removal of the probe secondary structure and spatial separation of the fluorescent and quenching moieties. A fluorescent signal results. A fluorescent signal indicates the presence of the flanking/transgene sequence due to successful amplification and hybridization.

The following examples are included to demonstrate examples of certain preferred embodiments of the invention. It should be appreciated by those of skill in the art that the techniques disclosed in the examples that follow represent approaches the inventors have found function well in the practice of the invention, and thus can be considered to constitute examples of preferred modes for its practice. However, those of skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments that are disclosed and still obtain a like or similar result without departing from the spirit and scope of the invention.

EXAMPLE 1

The transgenic wheat plants are generated by *Agrobacterium*-mediated transformation of wheat embryos by the method of Cheng et al. (Plant Physiol. 115:971-980, 1997) using the binary vectors of the present invention and a modification of the glyphosate selection conditions of Zhou et al. (Plant Cell Rep. 15:159-163, 1995). Other methods of wheat transformation are known to those skilled in the art of wheat transformation, such as, gene gun or particle bombardment and can be used to insert the expression cassettes of the present invention into the genome of wheat cells. The T-DNA of pMON30139 (FIG. 3) contains two expression cassettes that collectively confer a high level of tolerance to glyphosate herbicide. The first transgene expression cassette comprises DNA sequences of the rice actin 1 promoter and intron (P-Os.Act1 and I-Os.Act1, U.S. Pat. No. 5,641,876, herein incorporated by reference in its entirety), operably connected to a DNA sequence encoding

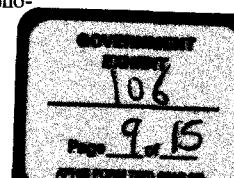
an *Arabidopsis thaliana* EPSPS chloroplast transit peptide (TS-At.EPSPS:CTP2, Klee et al., Mol. Gen. Genet. 210:47-442, 1987, herein incorporated by reference in its entirety), operably connected to a DNA sequence encoding a glyphosate resistant 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) isolated from *Agrobacterium tumefaciens* sp. strain CP4 (AGRTU.aroA gene, U.S. Pat. No. 5,633,435, herein incorporated by reference in its entirety), operably connected to a DNA sequence of a nopaline synthase transcriptional terminator (T-AGRTU.nos, Fraley et al., Proc. Natl. Acad. Sci. USA 80:4803-4807, 1983, herein incorporated by reference in its entirety). The second transgene expression cassette comprises a DNA sequence of a cauliflower mosaic virus 35S promoter containing a tandem duplication of the enhancer region (P-CaMV.35S:en, Kay et al., Science 236:1299-1302, 1987; U.S. Pat. No. 5,164,316, herein incorporated by reference in its entirety), operably connected to a DNA sequence of a *Zea mays* Hsp70 intron (I-Zm.Hsp70, U.S. Pat. No. 5,424,412, herein incorporated by reference in its entirety), operably connected to a DNA sequence encoding an *Arabidopsis thaliana* EPSPS chloroplast transit peptide sequence (TS-At.EPSPS, Klee et al., Mol. Gen. Genet. 210:47-442, 1987), operably connected to a DNA sequence encoding a glyphosate resistant 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) isolated from *Agrobacterium tumefaciens* sp. strain CP4 (AGRTU.aroA:CP4 gene, U.S. Pat. No. 5,633,435), operably connected to a DNA sequence of a nopaline synthase transcriptional terminator (T-AGRTU.nos, Fraley et al., Proc. Natl. Acad. Sci. USA 80:4803-4807, 1983).

pMON30167 (FIG. 1) is a single expression cassette identical to the first transgene expression cassette of pMON30139 as described above. pMON42411 (FIG. 2) is a single expression cassette identical to the second expression cassette of pMON30139 as described above.

After incubation of wheat cells with the *Agrobacterium* cells containing pMON42411, pMON30167 and pMON30139 constructs, glyphosate-tolerant transgenic wheat calli were selected on media containing 2 mM glyphosate for 1 week followed by transfer to a differentiation media with 0.1 mM glyphosate for 2 weeks and finally transfer to regeneration media with 0.02 mM glyphosate+0.1 μ M aromatic amino acids.

Two hundred eighty-four wheat events were produced from transformation with pMON42411, pMON30167 and pMON30139. These plants from pMON30139 and pMON30167 were sprayed once with 64 ounces/acre rate of glyphosate herbicide (Roundup Ultra®/acre) to select lines for vegetative and reproductive tolerance to glyphosate herbicide (Table 1). Plants from pMON42411 were sprayed twice with 64 ounces/acre rate of glyphosate herbicide. Selection of transformed wheat plants with the single expression cassettes of pMON42411 and pMON30167 resulted in a low percentage (1.4% and 3.2%, respectively) of wheat plants with both vegetative and reproductive tolerance. Only 3/134 plants from these constructs had acceptable levels of glyphosate herbicide tolerance. In contrast, transformed wheat plants containing the double expression cassette of pMON30139 produced a high percentage (16%) of plants with both vegetative and reproductive tolerance (24/150).

Wheat event 33391 (hence forth referred to as wheat plant 33391 or wheat 33391 and includes all plant parts and seed of this plant) was selected from the 150 transgenic wheat events produced from transformation with pMON30139. Twenty-four events were selected from this population that demonstrated improved vegetative and reproductive glypho-



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sate tolerance. Further evaluation of these 24 events was conducted for agronomic performance and the presence of a single intact insertion. Wheat 33391 was selected from this population of events. The greenhouse and field evaluations of wheat 33391 and progeny derived from wheat 33391 indicated that this transgenic insertion confers glyphosate tolerance that exceeds commercial specifications of full vegetative and reproductive tolerance to 340 g glyphosate/acre (840 g glyphosate/hectare; 32 oz of Roundup Ultra/acre) with two-fold safety margin when applied at the 3-5 leaf stage.

TABLE 1

Comparison of efficacy of single and double expression cassettes for conferring glyphosate tolerance in wheat			
pMON#	# events tested	# events with vegetative tolerance	# veg. tolerant events with reproductive tolerance
42411	71	26	1 (1.4%)
30167	63	4	2 (3.5%)
30139	150	104	24 (16%)

EXAMPLE 2

Isolation of the corresponding wheat genomic flanking sequence is possible by a variety of methods known to those skilled in the art (for example, using the ligated adapters and nested PCR as described in the Genome Walker™ kit, (CloneTech Laboratories, Inc, Palo Alto, Calif.). Genomic DNA from the wheat 33391 was isolated by CTAB purification method (Rogers et al., Plant Mol Biol 5:69-76, 1985). Reagents are available commercially (see, for example Sigma Chemical Co., St. Louis, Mo.). The genomic DNA libraries for amplification were prepared according to manufacturer instructions (Genome Walker™, CloneTech Laboratories, Inc, Palo Alto, Calif.). In separate reactions, genomic DNA was subjected to restriction enzyme digestion overnight at 37° C. with the following blunt-end endonucleases: DraI, EcoRV, Pvu II, Sca I, and Stu I (CloneTech Laboratories, Inc, Palo Alto, Calif.). The reaction mixtures were extracted with phenol:chloroform, the DNA was precipitated by the addition of ethanol to the aqueous phase, pelleted by centrifugation, then resuspended in Tris-EDTA buffer (10 mM Tris-HCl, pH 8.0, 1 mM EDTA). The purified blunt-ended genomic DNA fragments were then ligated to the Genome Walker™ adapters according to the manufacturer's protocol. After ligation of the adapters to the genomic DNA fragments, each reaction was heat treated (70° C. for 5 minutes) to terminate the reaction and then diluted 10-fold in Tris-EDTA buffer. One μ l of each respective ligation was then amplified in a 50 μ l reaction according to manufacturer's recommended protocol using an adapter-specific oligonucleotide (supplied by manufacturer) and a wheat 33391 transgene-specific oligonucleotide, such as SEQ ID NO:1, which anneals near the 5' end of the P-OsAct1. The PCR mixture contained 1 μ l of respective adapter-ligated library, 1 μ l of 10 μ M Genome Walker® adapter primer AP1 supplied by manufacturer (5'-GTATATCGACTCACTATAGGGC3', SEQ ID NO:11), 1 μ l of 10 μ M wheat 33391 transgene specific oligonucleotide (SEQ ID NO:1), 1 μ l of 10 mM deoxyribonucleotides, 5 μ l of 10 \times PCR buffer containing MgCl₂, 0.5 μ l (2.5 units) of Taq DNA polymerase (Boehringer Mannheim Biochemicals, Indianapolis, Ind.), and H₂O to 50 μ l. The PCR reactions were performed in a thermocycler using calculated temperature control and the following cycling conditions: 1 cycle of 94° C. for 1 minutes; 7 cycles of (94° C. for 2 seconds, 70° C. for 3 minutes); 37 cycles of (94° C. for 2 seconds, 65° C. for 3 minutes); 1 cycle of 65° C. for

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10 minutes. One μ l of each primary reaction was then amplified in a secondary amplification using a "nested" adapter-specific oligonucleotide (supplied by manufacturer) and a "nested" transgene-specific oligonucleotide such as SEQ ID NO:2, which anneals to P-OsAct1 upstream of the primer used in the primary reaction. The PCR mixture for secondary PCR contained 1 μ l of respective primary PCR products, 1 μ l of 10 μ M Genome Walker® nested adapter primer AP2 supplied by manufacturer (5'-ACTATAGGGCAGCGTGGT3', SEQ ID NO:12), 1 μ l of 10 μ M wheat 33391 transgene-specific nested oligonucleotide (SEQ ID NO:2), 1 μ l 10 mM deoxyribonucleotides, 5 μ l of 10 \times PCR buffer containing MgCl₂, 0.5 μ l (2.5 units) of Taq DNA polymerase (Boehringer Mannheim Biochemicals, Indianapolis, Ind.), and H₂O to 50 μ l. The PCR reactions were again performed in a thermocycler using calculated temperature control and the following cycling conditions: 1 cycle of 94° C. for 1 minute; 7 cycles of (94° C. for 2 seconds), 70° C. for 3 minutes; 31 cycles of (94° C. for 2 seconds, 65° C. for 3 minutes); 1 cycle of 65° C. for 10 minute. PCR products, representing 5" regions that span the junction between the wheat 33391 transgenic insertion and the neighboring flanking genomic sequence were then purified by agarose gel electrophoresis followed by isolation from the agarose matrix using the QIAquick Gel Extraction Kit (catalog # 28704, Qiagen Inc., Valencia, Calif.) and then directly cloned into the pGEM-T Easy vector (catalog # A1360, Promega, Madison, Wis.). The identity of the cloned PCR products was confirmed by DNA sequence analysis (ABI Prism™ 377, PE Biosystems, Foster City, Calif. and DNASTAR sequence analysis software, DNASTAR Inc., Madison, Wis.).

Similarly, the wheat 33391 3" flanking genomic DNA sequence was amplified and cloned using nested gene specific primers, such as SEQ ID NO:3, and SEQ ID NO:4, that anneal to the T-nos transcriptional terminator. Two T-nos transcriptional terminators are present in the wheat 33391 transgenic/genomic insertion, one internal in the construct and one at the 3' end of the construct adjacent to wheat genomic sequence. The PCR products produced in this reaction were sequenced and the DNA sequence that spans the junction between transgene and flanking genomic was distinguished from products of the internal T-nos by comparison to the known genetic element sequences of the pMON30139 construct.

Wheat genomic sequence flanking both sides of the transgene insertion site in the wheat genomic was determined for wheat 33391 by sequencing the Genome Walker®-derived amplification products and alignment to known transgene sequence. The sequence of a 399 base pairs (bp) segment around the insertion site was determined at the 5" end of the transgene insertion site. This segment consisted of 257 (bp) of wheat genomic sequence (nucleotide bases 1-257 of SEQ ID NO:5) and 93 bp of vector backbone sequence (nucleotide bases 258-350 of SEQ ID NO:5) and 49 bp of the 5" end of the rice Act1 promoter (nucleotide bases 251-399 of SEQ ID NO:5). Similarly, DNA sequence was determined for a 431 bp segment flanking the 3" insertion junction (SEQ ID NO:6), beginning with 32 bp of the T-nos transcriptional terminator sequence (nucleotide bases 1-32 of SEQ ID NO:6), 68 bp of vector backbone sequence (nucleotide bases 33-100) and ending with 331 bp of wheat genomic sequence flanking the transgene insertion site (nucleotide bases 101-431 of SEQ ID NO:6). Identification of wheat 33391 was performed by PCR amplification of the transgene/genomic insertion region using one primer from transgene sequence and another primer from the wheat genomic flanking sequence. The 5" transgene/genomic insertion region was confirmed by PCR amplification of a DNA amplicon to be unique to wheat 33391. This identification was demonstrated by a PCR amplicon generated by

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primer 5 (SEQ ID NO:7) and primer 6 (SEQ ID NO:8). Additional primer sequences can be synthesized using the DNA sequence shown in SEQ ID NO:5 that will generate amplicons of DNA length different than the amplicon generated by primer 5 and primer 6, but are still diagnostic for wheat 33391 and progeny thereof. It is within the ordinary skill in the art of a plant molecular biologist to select DNA primer sequences from SEQ ID NO:5 and develop stringent conditions for the production of an amplicon. Likewise, those skilled in the art can select DNA primer sequences from SEQ ID NO:6 that will generate amplicons diagnostic for wheat 33391. It is within the scope of this invention that DNA primer sequences derived from SEQ ID NO:5 and SEQ ID NO:6 are useful for the isolation of additional genomic DNA molecules from wheat 33391 plants, seeds and plant part by the methods disclosed herein or methods known in the art of plant molecular biologist. These additional wheat genomic DNA molecules can be isolated in a method that uses any portion of sufficient length of the DNA sequence disclosed in SEQ ID NO:5 and SEQ ID NO:6 useful as a primer or probe. The additional wheat genomic DNA molecules can be used as molecular markers diagnostic for wheat 33391.

DNA sequences that span the junction region of the wheat 33391 genomic DNA and the insert DNA of pMON30139 contained within SEQ ID NO:5 and SEQ ID NO:6 can be

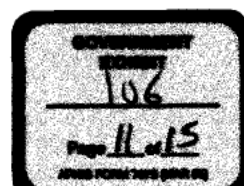
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used as probes in a hybridization reaction to identify DNA derived from wheat 33391. For example, a DNA molecule useful as a probe from SEQ ID NO:5 would comprise the nucleotide sequence occurring from position 245-270 or its complement; a DNA molecule useful as a probe from SEQ ID NO:6 would comprise the nucleotide sequence occurring from position 87-113 or its complement. Those skilled in the art can select nucleotide sequences shorter or longer in length than those afore described that span the junction region and are useful as specific DNA probes or primers for wheat 33391 under high stringency conditions.

The PCR reaction conditions (Table 2) and quality of the extracted wheat 33391 genomic DNA are confirmed by the production of an amplicon by primer 7 (SEQ ID NO:9) and primer 8 (SEQ ID NO:10) and representing an approximately 400 bp DNA fragment from the wheat acetyl CoA carboxylase gene (Acc), a single copy endogenous gene within the wheat genome. The controls for this analysis should include a positive control from wheat 33391, a negative control from a wheat plant that is not wheat 33391, and a negative control that contains no template wheat DNA as shown in Table 2. The assay for the wheat 33391 amplicon can be performed by using a Stratagene Robocycler, MJ Engine, Perkin-Elmer 9700, or Eppendorf Mastercycler Gradient thermocycler as shown in Table 3, or by methods and apparatus known to those skilled in the art.

TABLE 2

PCR procedure and reaction mixture for the confirmation of wheat 33391 5'			
Step	Reagent	Amount	Comments
1	Nuclease-free water	add to final volume of 20 μ l	—
2	10X reaction buffer (with $MgCl_2$)	2.0 μ l	1X final concentration of buffer, 1.5 mM final concentration of $MgCl_2$
3	10 mM solution of dATP, dCTP, dGTP, and dTTP	0.4 μ l	200 μ M final concentration of each dNTP
4	Primer 5 (SEQ ID NO:7) (resuspended in 1X TE buffer or nuclease-free water to a concentration of 10 μ M)	0.4 μ l	0.2 μ M final concentration
5	Primer 6 (SEQ ID NO:8) (resuspended in 1X TE buffer or nuclease-free water to a concentration of 10 μ M)	0.4 μ l	0.2 μ M final concentration
6	Primer 7 (SEQ ID NO:9) (resuspended in 1X TE buffer or nuclease-free water to a concentration of 10 μ M)	0.2 μ l	0.1 μ M final concentration
7	Primer 8 (SEQ ID NO:10) (resuspended in 1X TE buffer or nuclease-free water to a concentration of 10 μ M)	0.2 μ l	0.1 μ M final concentration
8	Rnase, Dnase free (500 ng/ μ l)	0.1 μ l	50 ng/reaction
9	REDTaq DNA polymerase (1 unit/ μ l)	1.0 μ l (recommended to switch pipets prior to next step)	1 unit/reaction
10	Extracted DNA (template): · Samples to be analyzed · individual leaves pooled · leaves (maximum of 50 leaves/pool) · Negative control · Negative control · Positive control	· 10-200 ng of genomic DNA · 200 ng of genomic DNA · 50 ng of wheat genomic DNA (not wheat 33391) · no template DNA · 50 ng of 33391 genomic DNA	—



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Table 3. Suggested PCR parameters for different thermocyclers.

Gently mix and, if needed (no hot top on thermocycler), add 1-2 drops of mineral oil on top of each reaction. Proceed with the PCR in a Stratagene Robocycler, MJ Engine, Perkin-Elmer 9700, or Eppendorf Mastercycler Gradient thermocycler using the following cycling parameters.

Note: The MJ Engine or Eppendorf Mastercycler Gradient thermocycler should be run in the calculated mode. Run the Perkin-Elmer 9700 thermocycler with the ramp speed set at maximum.

TABLE 3

Suggested PCR parameters for different thermocyclers. Gently mix and, if needed (no hot top on thermocycler), add 1-2 drops of mineral oil on top of each reaction. Proceed with the PCR in a Stratagene Robocycler, MJ Engine, Perkin-Elmer 9700, or Eppendorf Mastercycler Gradient thermocycler using the following cycling parameters.	
Cycle No.	Settings: Stratagene Robocycler
1	94° C. 3 minutes
38	94° C. 1 minute 63° C. 1 minute 72° C. 1 minute and 30 seconds
1	72° C. 10 minutes
Cycle No.	Settings: MJ Engine or Perkin-Elmer 9700
1	94° C. 3 minutes
38	94° C. 10 seconds 63° C. 30 seconds 72° C. 1 minute
1	72° C. 10 minutes
Cycle No.	Settings: Eppendorf Mastercycler Gradient
1	94° C. 3 minutes
38	94° C. 15 seconds 63° C. 15 seconds 72° C. 1 minute
1	72° C. 10 minutes

Note: The MJ Engine or Eppendorf Mastercycler Gradient thermocycler should be run in the calculated mode. Run the Perkin-Elmer 9700 thermocycler with the ramp speed set at maximum.

EXAMPLE 3

The expression of the glyphosate resistant EPSPS protein (CP4 EPSPS) from aroA:CP4 gene can be detected by immunological methods (Rogan et al., Food Control 10:407-414, 1999, herein incorporated by reference in its entirety) from plant tissue extracts. Immunological methods such as western blots, strip tests, and enzyme linked immunosorbent assays (ELISA) have been developed to specifically detect the protein expressed from the aroA:CP4 gene contained in plant expression vectors transformed into plants. Reagents that include the polyclonal and monoclonal antibodies specific for the CP4 EPSPS are commercially available from Strategic Diagnostics (Newark, Del.). CP4 EPSPS can be detected from protein extracts of wheat 33391 plants, plant parts and seeds by immunological methods that include ELISA.

An ELISA procedure that uses 100 ng of monoclonal anti-CP4 EPSPS antibody diluted in 100 μ l of 0.05 M carbonate-bicarbonate buffer pH 9.6 is absorbed to the well of a microtiter plate overnight at 4° C. The well is washed with phosphate buffered saline 0.05% Tween-20, pH 7.4 (PBS-T). The tissue is homogenized in phosphate buffered saline with a mortar and pestle or other suitable tissue grinder. The homogenate is added to the well of the microtiter plate and incubated for about 2 hours at 37° C. The well is washed three times with PBS-T. In one method, a secondary antibody, a purified rabbit anti-CP4 EPSPS is diluted to a sufficient level to provide specific binding to the

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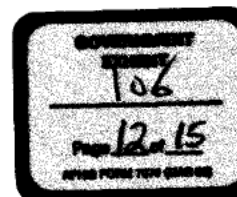
CP4-EPSPS protein and incubated at 37° C. for about 1 hour. In a second method, a secondary antibody, a goat anti-CP4 EPSPS is used. A biotin-conjugated Mab anti-rabbit IgG or anti-goat IgG (Sigma Corp, St Louis Mo.) is added to the well (1:40,000 dilution in PBS) and incubated at 37° C. for 30 minutes. The well is washed three times with PBS-T. NeutrAvidin conjugated Horse radish peroxidase is diluted 1:10,000 using StabilZyme HRP-stabilizer (SurModics, Eden Prairie, Minn.) and incubated at 37° C. for 15 minutes. The well is washed three times with PBS-T. The TMB substrate (Kirkegaard and Perry, Gaithersburg, Md.) is added for 10 minutes, then reaction quenched using 3 M phosphoric acid. The well is read with a microtiter plate reader at 450 nm using a reference wavelength of 650 nm. This method is an example of an ELISA suitable for detection of CP4 EPSPS and is not intended to be the only ELISA method that can be used to detect CP4 EPSPS, those skilled in the art of ELISA will know that variations to the method can be designed to provide a detection assay specific and sufficiently sensitive to detect CP4 EPSPS in a plant tissue extract.

ELISA of field grown forage of wheat event 33391 contain a mean level of 58.2+8.4 μ g/g, with a range of 45.5 to 72.4 μ g/g, CP4 EPSPS protein on a fresh weight tissue (fw) basis, while the non-transgenic control forage had no detectable level of the CP4 EPSPS protein above the ELISA method's limit of detection at 0.9 μ g/g fw. Wheat event 33391 grain tissues contain a mean level of 12.6+2.5 μ g/g, with a range of 9.5 to 17.6 μ g/g, CP4 EPSPS protein on a fresh weight tissue (fw) basis, while the non-transgenic control forage had no detectable level of the CP4 EPSPS protein above the ELISA method's limit of detection at 0.1 μ g/g fw. ELISA or other immunological methods for detecting CP4 EPSPS can be used as a diagnostic test for wheat 33391, when wheat 33391 progeny are the only USDA (United States Department of Agriculture) registered glyphosate tolerant wheat that expresses the CP4 EPSPS protein.

A deposit of the Monsanto Company, wheat 33391 disclosed above and recited in the appended claims has been made under the Budapest Treaty with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Va. 20110. The ATCC accession number is PTA-2347. The deposit will be maintained in the depository for a period of 30 years, or 5 years after the last request, or for the effective life of the patent, whichever is longer, and will be replaced as necessary during that period. Having illustrated and described the principles of the present invention, it should be apparent to persons skilled in the art that the invention can be modified in arrangement and detail without departing from such principles. We claim all modifications that are within the spirit and scope of the appended claims.

All publications and published patent documents cited in this specification are incorporated herein by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

An electronic file containing the sequence listing was filed concurrently with this specification. The file name is 38-21 (52232)A.



SEQUENCE LISTING

<160> NUMBER OF SEQ ID NOS: 12

<210> SEQ ID NO 1

<211> LENGTH: 32

<212> TYPE: DNA

<213> ORGANISM: *Oryza sativa*

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<210> SEQ ID NO 2

<211> LENGTH: 30

<212> TYPE: DNA

<213> ORGANISM: *Oryza sativa*

<400> SEQUENCE: 2

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<210> SEQ ID NO 3

<211> LENGTH: 27

<212> TYPE: DNA

<213> ORGANISM: *Agrobacterium tumefaciens*

<400> SEQUENCE: 3

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<210> SEQ ID NO 4

<211> LENGTH: 30

<212> TYPE: DNA

<213> ORGANISM: *Agrobacterium tumefaciens*

<400> SEQUENCE: 4

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<212> TYPE: DNA

<213> ORGANISM: Artificial Sequence

<220> FEATURE:

<221> NAME/KEY: misc_feature

<222> LOCATION: (1)..(399)

<223> OTHER INFORMATION: chimeric sequence of wheat genome and transgene insert

<400> SEQUENCE: 5

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ttctgtatcc acgagatccc atcttggggc ctgttcggga gctccgccgg acgagggccg 120

tcatacagga tggttcttgc atcatcatag cctctccgat gaagtgtgag tagtttacct 180

cagaccttcg ggtccatagt tagtagctag atggcttctt ctctctcttt gaatctcaat 240

acaaagttct cccctctct aattcggaaa tctttatttc gacgtgtcta cattcacgtc 300

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gaggtcattc atatgcttga gaagagagtc gggatagtc 399

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<211> LENGTH: 431

<212> TYPE: DNA

<213> ORGANISM: Artificial Sequence

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<221> NAME/KEY: misc_feature

<222> LOCATION: (1)..(431)

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<223> OTHER INFORMATION: chimeric sequence of wheat genome and transgene insert

<400> SEQUENCE: 6

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aataattatg acgatgtcca ggcactgac aatacatagg catcacgtcg aagattagta    180
gatcgaagat tagtagactg acgatgtcca ggcactgac aatacatagg gatcggggat    240
aaccaaaata ctgttgggca attgatagaa cctcaaataa ttatgacgat gtccaggcac    300
tgatcaatac ataggcatca cgtcgaagat tagtagaccg actccttcct gcactacta    360
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<211> LENGTH: 24

<212> TYPE: DNA

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<400> SEQUENCE: 8

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<400> SEQUENCE: 9

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<212> TYPE: DNA

<213> ORGANISM: *Triticum aestivum*

<400> SEQUENCE: 10

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<221> NAME/KEY: misc_feature

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<223> OTHER INFORMATION: fully synthetic sequence

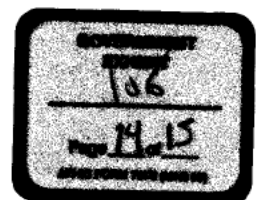
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<210> SEQ ID NO 12

<211> LENGTH: 19

<212> TYPE: DNA



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<213> ORGANISM: Artificial Sequence
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<221> NAME/KEY: misc_feature
<222> LOCATION: (1)..(19)
<223> OTHER INFORMATION: fully synthetic sequence

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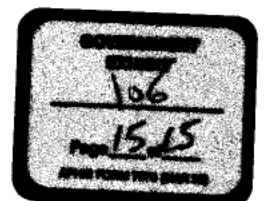
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We claim:

1. An isolated DNA molecule comprising the nucleotide sequence of SEQ ID NO: 5.

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US007268274B2

(12) **United States Patent**
Chen et al.

(10) **Patent No.:** US 7,268,274 B2
(45) **Date of Patent:** Sep. 11, 2007

(54) **GLYPHOSATE TOLERANT WHEAT PLANT 33391 AND COMPOSITIONS AND METHODS FOR DETECTION THEREOF**

(75) **Inventors:** Guilan Chen, Chesterfield, MO (US); Catherine M. Hironaka, Dublin, CA (US); Hua-ping Zhou, Chesterfield, MO (US)

(73) **Assignee:** Monsanto Technology LLC, St. Louis, MO (US)

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 235 days.

(21) **Appl. No.:** 10/727,423

(22) **Filed:** Dec. 4, 2003

(65) **Prior Publication Data**

US 2004/0133939 A1 Jul. 8, 2004

Related U.S. Application Data

(62) Division of application No. 09/682,597, filed on Sep. 25, 2001, now Pat. No. 6,689,880.

(60) Provisional application No. 60/236,762, filed on Sep. 29, 2000, provisional application No. 60/236,653, filed on Sep. 29, 2000.

(51) **Int. Cl.**

A01H 5/00 (2006.01)

A01H 5/10 (2006.01)

C12N 15/82 (2006.01)

(52) **U.S. Cl.** 800/300; 800/278; 800/298; 800/320.3

(58) **Field of Classification Search** 800/278, 800/320.3, 800

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,633,435 A 5/1997 Barry et al.
5,948,956 A 9/1999 Lee et al.
5,990,390 A * 11/1999 Lundquist et al. 800/302
6,645,765 B1 * 11/2003 Anderson et al. 435/410

FOREIGN PATENT DOCUMENTS

EP 1 167 531 A1 1/2002
WO WO 99/46396 9/1999
WO WO99/46396 * 9/1999 800/300

OTHER PUBLICATIONS

Zhou et al 1995 Plant Cell Reports 15: 159-163.*
Saroja et al., Glyphosate tolerant crops: genes and enzymes, *J. Plant Biochem and Biotech*, 7: 65-72 (1998).
Windels et al., Development of a line specific GMO detection method a case study, *Med., Fac. Landbouww. Univ. Gent. 64/5b*: 459-62 (1999).
Zhou et al., Glyphosate tolerant CP4 and GOX genes as a selectable marker in wheat transformation, *Plant Cell Reports* 15:159-63 (1995).

* cited by examiner

Primary Examiner—David H Kruse

(74) *Attorney, Agent, or Firm*—M. Todd Rands; Howrey LLP

(57) **ABSTRACT**

The present invention provides a DNA construct composition that relates to transgenic glyphosate tolerant wheat plants. The invention relates to the wheat plant 33391, the progeny thereof and to methods for the detection of wheat plant 33391 and its progeny and compositions thereof.

5 Claims, 3 Drawing Sheets

OR120018_BR_003224



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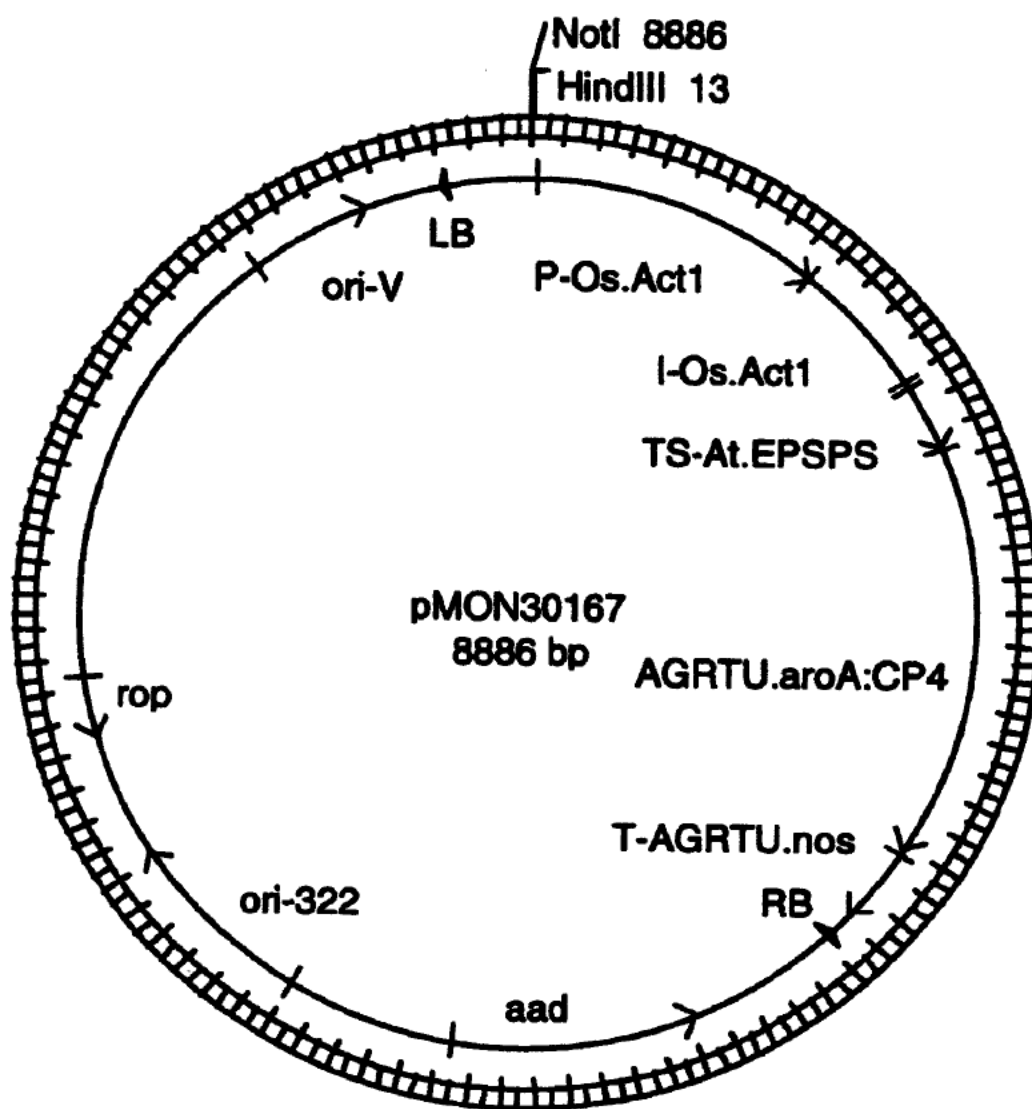
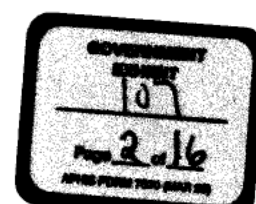


Figure 1



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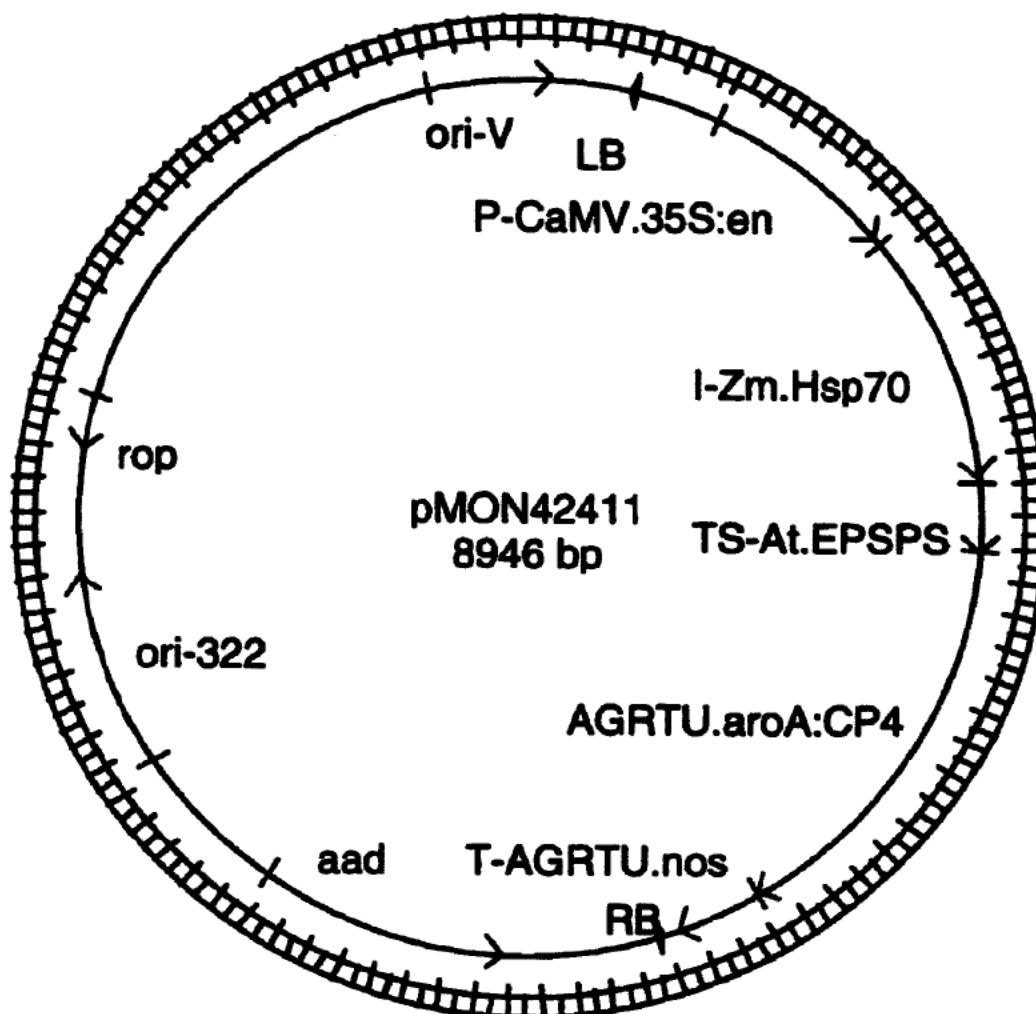


Figure 2

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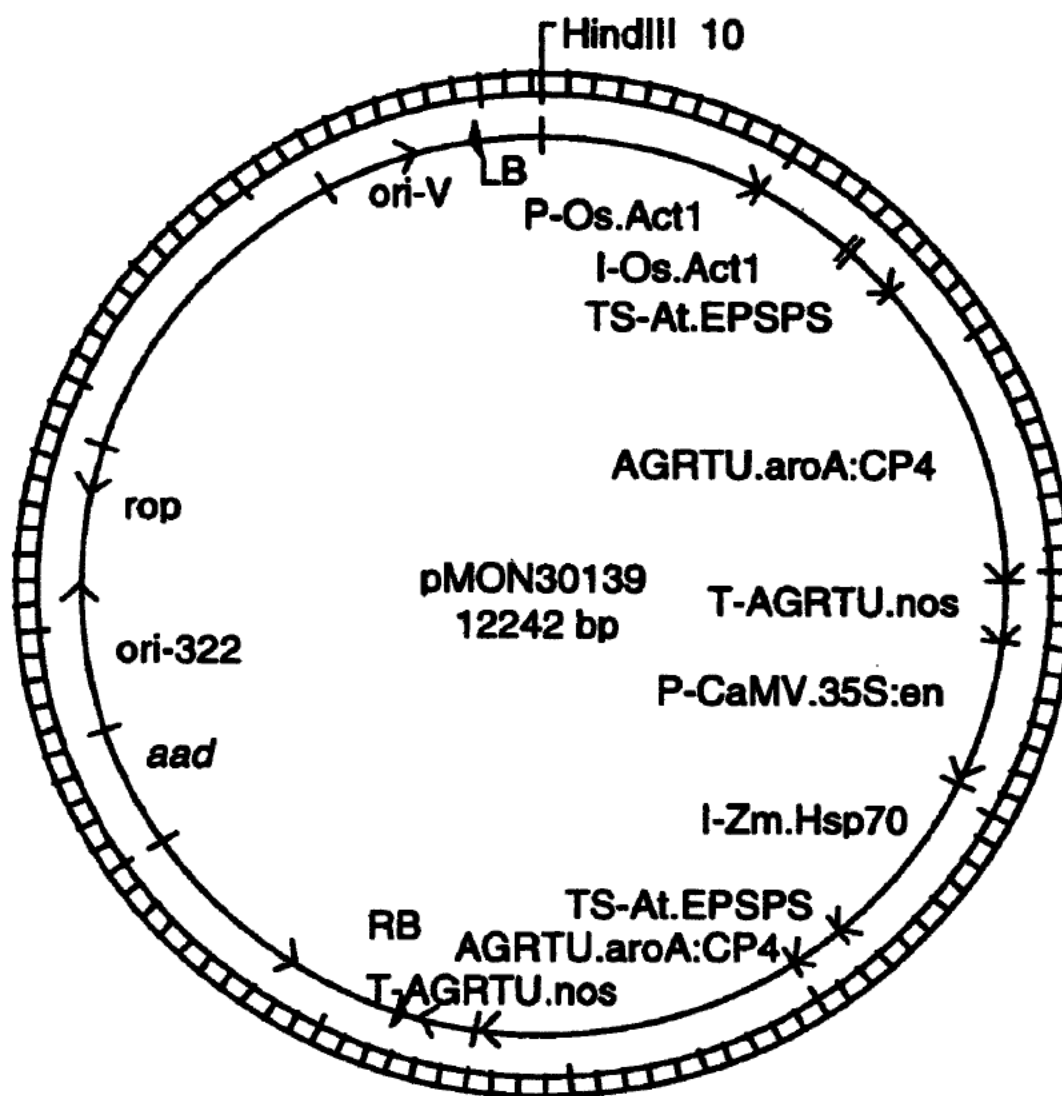


Figure 3

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GLYPHOSATE TOLERANT WHEAT PLANT 33391 AND COMPOSITIONS AND METHODS FOR DETECTION THEREOF

This application is a divisional application of U.S. application Ser. No. 09/682,597 filed Sep. 25, 2001 (now issued as U.S. Pat. No. 6,689,880) which claims the benefit of U.S. Provisional Application No. 60/236,762, filed Sep. 29, 2000 and U.S. Provisional Application No. 60/236,653 filed Sep. 29, 2000.

FIELD OF THE INVENTION

The present invention relates to the field of plant molecular biology, more specifically the invention relates to a DNA construct for conferring improved glyphosate tolerance to a wheat plant. The invention more specifically relates to a glyphosate tolerant wheat plant 33391 and progeny thereof and to assays for detecting the presence of wheat plant 33391 DNA in a sample and compositions thereof.

BACKGROUND OF THE INVENTION

Wheat is an important crop and is a primary food source in many areas of the world. The methods of biotechnology have been applied to wheat for improvement of the agronomic traits and the quality of the product. One such agronomic trait is herbicide tolerance, in particular, tolerance to glyphosate herbicide. This trait in wheat is conferred by the expression of a transgene in the wheat plants (Zhou et al., Plant Cell Rep. 15:159-163, 1995). The expression of foreign genes in plants is known to be influenced by their chromosomal position, perhaps due to chromatin structure (e.g., heterochromatin) or the proximity of transcriptional regulation elements (e.g., enhancers) close to the integration site (Weising et al., Ann. Rev. Genet. 22:421-477, 1988). For this reason, it is often necessary to screen a large number of events in order to identify an event characterized by optimal expression of a introduced gene of interest. For example, it has been observed in plants and in other organisms that there may be a wide variation in levels of expression of an introduced gene among events. There may also be differences in spatial or temporal patterns of expression, for example, differences in the relative expression of a transgene in various plant tissues, that may not correspond to the patterns expected from transcriptional regulatory elements present in the introduced gene construct. For this reason, it is common to produce hundreds to thousands of different events and screen those events for a single event that has desired transgene expression levels and patterns for commercial purposes. An event that has desired levels or patterns of transgene expression is useful for introgressing the transgene into other genetic backgrounds by sexual outcrossing using conventional breeding methods. Progeny of such crosses maintain the transgene expression characteristics of the original transformant. This strategy is used to ensure reliable gene expression in a number of varieties that are well adapted to local growing conditions.

It would be advantageous to be able to detect the presence of a particular event in order to determine whether progeny of a sexual cross contain a transgene of interest. In addition, a method for detecting a particular event would be helpful for complying with regulations requiring the premarket approval and labeling of foods derived from recombinant crop plants, for example. It is possible to detect the presence of a transgene by any well known nucleic acid detection method such as the polymerase chain reaction (PCR) or

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DNA hybridization using nucleic acid probes. These detection methods generally focus on frequently used genetic elements, such as promoters, terminators, marker genes, etc. As a result, such methods may not be useful for discriminating between different events, particularly those produced using the same DNA construct unless the sequence of chromosomal DNA adjacent to the inserted DNA ("flanking DNA") is known. An event-specific PCR assay is discussed, for example, by Windels et al. (Med. Fac. Landbouww. Univ. Gent 64/5b:459-462, 1999), who identified glyphosate tolerant soybean event 40-3-2 by PCR using a primer set spanning the junction between the insert and flanking DNA, specifically one primer that included sequence from the insert and a second primer that included sequence from flanking DNA.

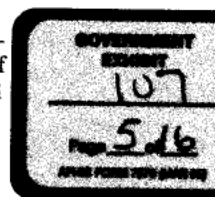
This invention relates to the improved glyphosate herbicide tolerant wheat (*Triticum aestivum*) plant 33391 and to a DNA plant expression construct of wheat plant 33391 and the detection of the transgene/genomic insertion region in wheat 33391 and progeny thereof.

SUMMARY OF THE INVENTION

According to one aspect of the invention, a DNA construct is provided that when expressed in wheat plant cells and wheat plants confers improved tolerance to glyphosate herbicide. This invention relates to the methods for producing and selecting a glyphosate tolerant wheat plant containing the DNA construct pMON30139. The DNA construct, pMON30139 consists of two transgene expression cassettes. The first expression cassette consists of a rice (*Oryza sativa*) actin 1 promoter (P-Os.Act1) and intron (I-Os.Act1) operably joined to an *Arabidopsis* EPSPS chloroplast transit peptide sequence (TS-At.EPSPS), operably connected to a gene (AGRTU.aroA:CP4) encoding a glyphosate resistant 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) isolated from *Agrobacterium tumefaciens* (AGRTU) sp. strain CP4, operably connected to a nopaline synthase transcriptional terminator (T-AGRTU.nos). The second transgene expression cassette consists of the cauliflower mosaic virus (CaMV) 35S promoter (P-CaMV.35S:en) containing a tandem duplication of the enhancer region, operably connected to a *Zea mays* Hsp70 intron (I-Zm.Hsp70), operably connected to a nucleic acid sequence encoding an *Arabidopsis thaliana* EPSPS chloroplast transit peptide sequence, operably connected to a gene encoding a glyphosate resistant 5-enol-pyruvylshikimate-3-phosphate synthase isolated from *Agrobacterium tumefaciens* sp. strain CP4, operably connected to a nopaline synthase transcriptional terminator. These expression cassettes are in tandem and flanked by DNA regions that contain *Agrobacterium tumefaciens* DNA sequences (RB and LB) as a components of the process that is used in an *Agrobacterium* mediated method to insert of the expression cassettes into a wheat genome.

According to another aspect of the invention, wheat 33391 seed comprising such DNA molecules are provided as deposited with the ATCC, accession #PTA-2347. This aspect of the invention thus relates to the seeds of wheat 33391, to the plants of wheat 33391, to the plant parts of wheat 33391 that includes pollen and ovules, and to the methods for producing an improved glyphosate tolerant wheat plant by crossing the wheat plant 33391 with itself or another wheat plant.

According to another aspect of the invention, compositions and methods are provided for detecting the presence of the transgene/genomic insertion region from wheat 33391



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plants and seeds. According to one aspect of the invention, DNA molecules are provided that comprise at least one transgene/genomic insertion region sequence of wheat 33391 selected from the group consisting of SEQ ID NO:5 and SEQ ID NO:6 and complements thereof, wherein an insertion region sequence spans the junction between heterologous DNA inserted into the wheat genome and DNA from the wheat genome flanking the insertion site and is diagnostic for the event. Included are DNA sequences that comprise a sufficient length of polynucleotides of transgene insert sequence and a sufficient length of polynucleotides of wheat genomic sequence from wheat 33391 of SEQ ID NO:5 that are useful as primer sequences for the production of an amplicon product diagnostic for wheat 33391. Included are DNA sequences that comprise a sufficient length of polynucleotides of transgene insert sequence and a sufficient length of polynucleotides of wheat genomic sequence from wheat 33391 of SEQ ID NO:6 that are useful as primer sequences for the production of an amplicon product diagnostic for wheat 33391.

According to another aspect of the invention DNA molecules are provided that are diagnostic for wheat 33391. This aspect of the invention is directed to the wheat 33391 containing at least one novel DNA molecule. DNA molecules comprising nucleic acid primers are provided that provide at least one novel DNA amplicon product of wheat 33391 consisting of SEQ ID NO:7 and SEQ ID NO:8, or the complements thereof. Such DNA amplicons are diagnostic for wheat 33391. Nucleic acid amplification of genomic DNA of the wheat 33391 produces an amplicon comprising such diagnostic DNA sequences. The invention provides isolated DNA molecules that comprise a sufficient length of transgene insert sequence and a sufficient length of wheat genomic sequence from wheat 33391 to function as primer sequences for the production of an amplicon product diagnostic for wheat 33391.

According to another aspect of the invention, methods of detecting the presence of DNA corresponding to the wheat 33391 in a sample are provided. Such methods comprise: (a) contacting the sample comprising DNA with a primer set that, when used in a nucleic-acid amplification reaction with genomic DNA from wheat 33391, produces an amplicon that is diagnostic for wheat 33391; (b) performing a nucleic acid amplification reaction, thereby producing the amplicon; and (c) detecting the amplicon.

According to another aspect of the invention, a kit is provided for the detection of wheat 33391. The kit includes at least one DNA sequence of sufficient length of polynucleotides complementary to SEQ ID NO:5 or SEQ ID NO:6, wherein the DNA sequences are useful as primers or probes that hybridize to isolated DNA from wheat 33391 or its progeny.

According to another aspect of the invention, methods of producing a wheat plant with improved tolerance to glyphosate are provided that comprise the steps of: (a) sexually crossing a first parental wheat line comprising the pMON30139 construct that confers improved tolerance to application of glyphosate, and a second parental wheat line that lacks glyphosate tolerance, thereby producing a plurality of progeny plants; and (b) selecting a progeny plant that tolerates application of glyphosate. Such methods are useful for introgressing the glyphosate tolerant trait into different genetic backgrounds. Such methods may optionally comprise the further step of back-crossing the progeny plant to the second parental wheat line to produce a wheat plant that tolerates application of glyphosate.

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The foregoing and other aspects of the invention will become more apparent from the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1. Plasmid map of pMON30167

FIG. 2. Plasmid map of pMON42411

FIG. 3. Plasmid map of pMON30139

DETAILED DESCRIPTION OF THE EMBODIMENTS

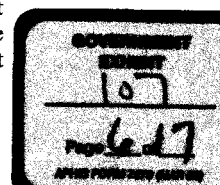
The following definitions and methods are provided to better define the present invention and to guide those of ordinary skill in the art in the practice of the present invention. Unless otherwise noted, terms are to be understood according to conventional usage by those of ordinary skill in the relevant art. Definitions of common terms in molecular biology may also be found in Rieger et al., *Glossary of Genetics: Classical and Molecular*, 5th edition, Springer-Verlag: New York, 1991; and Lewin, *Genes V*, Oxford University Press: New York, 1994. The nomenclature for DNA bases as set forth at 37 CFR § 1.822 is used.

As used herein, the term "wheat" means *Triticum aestivum* (including spring, winter, and facultative wheat varieties) any other wheat species that can be bred with *Triticum aestivum*, including but not limited to durum wheat (*Triticum durum*), spelt (*Triticum spelta*), and emmer (*Triticum dicoccum*). Also encompassed are plants that are produced by conventional techniques using *Triticum aestivum* as a parent in a sexual cross with a non-*Triticum* species (such as rye [*Secale cereale*]), including but not limited to triticale.

As used herein, the term "comprising" means "including but not limited to".

"Glyphosate" refers to N-phosphonomethylglycine and its salts. Glyphosate is the active ingredient of Roundup® herbicide (Monsanto Co, St. Louis, Mo.). Treatments with "glyphosate herbicide" refer to treatments with the Roundup®, Roundup Ultra® herbicide or any other formulation containing glyphosate. For the purposes of the present invention, the term "glyphosate" includes any herbicidally active form of N-phosphonomethylglycine (including any salt thereof) and other forms that result in the production of the glyphosate anion in plants. Treatments with "glyphosate" refer to treatments with the Roundup® or Roundup Ultra® herbicide formulation, unless otherwise stated. Plant transformation and regeneration in tissue culture use glyphosate or salts of glyphosate. Whole plant assays use formulated Roundup® or Roundup Ultra®. Additional formulations with herbicide activity that contain N-phosphonomethylglycine or any of its salts are herein included as a glyphosate herbicide.

A transgenic "event" is produced by transformation of plant cells with heterologous DNA, i.e., a nucleic acid construct that includes a transgene of interest, regeneration of a population of plants resulting from the insertion of the transgene into the genome of the plant, and selection of a particular plant characterized by insertion into a particular genome location. The term "event" refers to the original transformant and progeny of the transformant that include the heterologous DNA. The term "event" also refers to progeny produced by a sexual outcross between the transformant and another variety that include the heterologous DNA. Even after repeated back-crossing to a recurrent parent, the inserted DNA and flanking DNA from the transformed parent is present in the progeny of the cross at



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the same chromosomal location. The term "event" also refers to DNA from the original transformant and progeny thereof comprising the inserted DNA and flanking genomic sequence immediately adjacent to the inserted DNA that would be expected to be transferred to a progeny that receives inserted DNA including the transgene of interest as the result of a sexual cross of one parental line that includes the inserted DNA (e.g., the original transformant and progeny resulting from selfing) and a parental line that does not contain the inserted DNA. The "event" of the present invention comprises wheat 33391 seed having ATCC accession No. PTA-2347 and wheat plants grown from the wheat 33391 and progeny thereof. A wheat plant that tolerates a sufficient amount of glyphosate herbicide to control the weeds in a field without affecting the wheat plant can be bred by first sexually crossing a first parental wheat plant consisting of a wheat plant containing the expression cassettes of pMON30139 that confers improved tolerance to application of glyphosate herbicide, and a second parental wheat plant that lacks the tolerance to glyphosate herbicide, thereby producing a plurality of first progeny plants; and then selecting a first progeny plant that is tolerant to application of glyphosate herbicide; and selfing the first progeny plant, thereby producing a plurality of second progeny plants; and then selecting from the second progeny plants a glyphosate herbicide tolerant plant. These steps can further include the back-crossing of the first glyphosate tolerant progeny plant or the second glyphosate tolerant progeny plant to the second parental wheat plant or a third parental wheat plant, thereby producing a wheat plant that tolerates the application of glyphosate herbicide. A wheat crop comprising wheat 33391 seeds or progeny thereof can be planted in a field and treated with a sufficient amount of glyphosate herbicide to control the weeds without significantly affecting the wheat crop. A sufficient amount of glyphosate herbicide is about 8 ounces/acre or more, 16 ounces/acre or more, 32 ounces/acre or more, or 64 ounces/acre or more. Any glyphosate containing herbicide formulation can be used to control weeds in a wheat crop comprising wheat 33391 plants or progeny thereof.

It is also to be understood that two different transgenic plants can also be mated to produce offspring that contain two independently segregating added, exogenous genes. Selfing of appropriate progeny can produce plants that are homozygous for both added, exogenous genes that encode a polypeptide of interest. Back-crossing to a parental plant and out-crossing with a non-transgenic plant are also contemplated, as is vegetative propagation. Descriptions of other breeding methods that are commonly used for different traits and crops can be found in one of several references, e.g., Fehr, in *Breeding Methods for Cultivar Development*, Wilcox J. ed., American Society of Agronomy, Madison Wis. (1987) herein incorporated by reference in its entirety; Poehlman, J. M. (1987); *Breeding Field Crops*, 3rd ed. Van Nostrand Reinhold, N.Y., Knott, D. R. (1987); herein incorporated by reference in its entirety. The Application of Breeding Procedures to Wheat, p. 419-427. In E. G. Heyne (ed.) In "Wheat and Wheat Improvement", Madison, Wis. herein incorporated by reference in its entirety. Backcross breeding has been used to transfer genes for a simply inherited, highly heritable trait into a desirable homozygous cultivar or inbred line, which is the recurrent parent. The source of the trait to be transferred is called the donor parent. The resulting plant is expected to have the attributes of the recurrent parent (e.g., cultivar) and the desirable trait transferred from the donor parent. After the initial cross, individuals possessing the phenotype of the donor parent are

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selected and repeatedly crossed (backcrossed) to the recurrent parent. The resulting parent is expected to have the attributes of the recurrent parent (e.g., cultivar) and the desirable trait transferred from the donor parent.

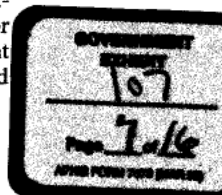
The DNA molecules of the present invention can be used as molecular markers in a marker assisted breeding (MAB) method. DNA molecules of the present invention can be used in methods, such as, AFLP markers, RFLP markers, RAPD markers, SNPs, and SSRs that identify genetically linked agronomically useful traits as described by Walton, *Seed World* 22-29 (July, 1993), the entirety of which is herein incorporated by reference; Burow and Blake, *Molecular Dissection of Complex Traits*, 13-29, Eds. Pater-son, CRC Press, New York (1988), the entirety of which is herein incorporated by reference. The improved glyphosate tolerance trait of wheat plant 33391 can be tracked in the progeny of a cross with wheat plant 33391 and any other wheat cultivar or variety using the MAB methods. The DNA molecules are markers for this trait and in MAB methods that are well known in the art can be used to track glyphosate tolerance in wheat where wheat plant 33391 was a parent or ancestor.

A "probe" is an isolated nucleic acid to which is attached a conventional detectable label or reporter molecule, e.g., a radioactive isotope, ligand, chemiluminescent agent, or enzyme. Such a probe is complementary to a strand of a target nucleic acid, in the case of the present invention, to a strand of genomic DNA from wheat event 33391 (whether from a wheat plant or from a sample that includes DNA from the event). Probes according to the present invention include not only deoxyribonucleic or ribonucleic acids but also polyamides and other probe materials that bind specifically to a target DNA sequence and can be used to detect the presence of that target DNA sequence.

"Primers" are isolated nucleic acids that are annealed to a complementary target DNA strand by nucleic acid hybridization to form a hybrid between the primer and the target DNA strand, then extended along the target DNA strand by a polymerase, e.g., a DNA polymerase. Primer pairs or sets can be used for amplification of a nucleic acid sequence, e.g., by the polymerase chain reaction (PCR) or other conventional nucleic-acid amplification methods.

Probes and primers are generally 8 polynucleotides or more in length, 18 polynucleotides or more, 24 polynucleotides or more, 30 polynucleotides or more. Polynucleotides useful as probes and primers that are of sufficient length to hybridize specifically to a target sequence under stringent conditions for hybridization. Probes and primers according to the present invention have complete sequence similarity with the target sequence, although probes differing from the target sequence and that retain the ability to hybridize to target sequences may be designed by conventional methods.

Methods for preparing and using probes and primers are described, for example, in *Molecular Cloning: A Laboratory Manual*, 2nd ed., vol. 1-3, ed. Sambrook et al., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., 1989 (hereinafter, "Sambrook et al., 1989") herein incorporated by reference in its entirety; *Current Protocols in Molecular Biology*, ed. Ausubel et al., Greene Publishing and Wiley-Interscience, New York, 1992 (with periodic updates) (hereinafter, "Ausubel et al., 1992") herein incorporated by reference in its entirety; and Innis et al., *PCR Protocols: A Guide to Methods and Applications*, Academic Press: San Diego, 1990 herein incorporated by reference in its entirety. PCR-primer pairs can be derived from a known sequence, for example, by using computer programs intended for that purpose such as Primer (Version 0.5, © 1991, Whitehead



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Institute for Biomedical Research, Cambridge, Mass.) herein incorporated by reference in its entirety.

Primers and probes based on the flanking DNA and insert sequences disclosed herein can be used to confirm (and, if necessary, to correct) the disclosed sequences by conventional methods, e.g., by re-cloning and sequencing such sequences.

The nucleic-acid probes and primers of the present invention hybridize under stringent conditions to a target DNA sequence. Any conventional nucleic acid hybridization or amplification method can be used to identify the presence of DNA from a transgenic event in a sample.

The term "stringent conditions" is functionally defined with regard to the hybridization of a nucleic-acid probe to a target nucleic acid (i.e., to a particular nucleic-acid sequence of interest) by the specific hybridization procedure discussed in Sambrook et al., 1989, at 9.52-9.55. See also, Sambrook et al., 1989 at 9.47-9.52, 9.56-9.58 herein incorporated by reference in its entirety; Kanehisa, (Nucl. Acids Res. 12:203-213, 1984, herein incorporated by reference in its entirety); and Wetmur and Davidson, (J. Mol. Biol. 31:349-370, 1988, herein incorporated by reference in its entirety). Accordingly, the nucleotide sequences of the invention may be used for their ability to selectively form duplex molecules with complementary stretches of DNA fragments. Depending on the application envisioned, one will desire to employ varying conditions of hybridization to achieve varying degrees of selectivity of probe towards target sequence. For applications requiring high selectivity, one will typically desire to employ relatively stringent conditions to form the hybrids, e.g., one will select relatively low salt and/or high temperature conditions, such as provided by about 0.02 M to about 0.15 M NaCl at temperatures of about 50° C. to about 70° C. A stringent conditions, for example, is to wash the hybridization filter at least twice with high-stringency wash buffer (0.2×SSC, 0.1% SDS, 65° C). Appropriate stringency conditions which promote DNA hybridization, for example, 6.0× sodium chloride/sodium citrate (SSC) at about 45° C., followed by a wash of 2.0×SSC at 50° C., are known to those skilled in the art or can be found in *Current Protocols in Molecular Biology*, John Wiley & Sons, N.Y. (1989), 6.3.1-6.3.6. For example, the salt concentration in the wash step can be selected from a low stringency of about 2.0×SSC at 50° C. to a high stringency of about 0.2×SSC at 50° C. In addition, the temperature in the wash step can be increased from low stringency conditions at room temperature, about 22° C., to high stringency conditions at about 65° C. Both temperature and salt may be varied, or either the temperature or the salt concentration may be held constant while the other variable is changed. Such selective conditions tolerate little, if any, mismatch between the probe and the template or target strand. Detection of DNA sequences via hybridization is well-known to those of skill in the art, and the teachings of U.S. Pat. Nos. 4,965,188 and 5,176,995 are exemplary of the methods of hybridization analyses.

Regarding the amplification of a target nucleic-acid sequence (e.g., by PCR) using a particular amplification primer pair, "stringent conditions" are conditions that permit the primer pair to hybridize only to the target nucleic-acid sequence to which a primer having the corresponding wild-type sequence (or its complement) would bind and preferably to produce a unique amplification product, the amplicon.

The term "specific for (a target sequence)" indicates that a probe or primer hybridizes under stringent hybridization conditions only to the target sequence in a sample comprising the target sequence.

As used herein, "amplified DNA" or "amplicon" refers to the product of nucleic acid amplification of a target nucleic acid sequence that is part of a nucleic acid template. For example, to determine whether the wheat plant resulting from a sexual cross contains an transgenic event, genomic DNA from a wheat plant may be subjected to nucleic acid amplification using a primer pair that includes a primer derived from flanking sequence in the genome of the plant adjacent to the insertion site of inserted heterologous DNA and a second primer derived from the inserted heterologous DNA to produce an amplicon that is diagnostic for the presence of the event. The amplicon is of a length and has a sequence that is diagnostic for the event. Alternatively, a primer pair can be derived from flanking sequence on both sides of the inserted DNA so as to produce an amplicon that includes the entire insert.

Nucleic acid amplification can be accomplished by any of the various nucleic acid amplification methods known in the art, including the polymerase chain reaction (PCR). A variety of amplification methods are known in the art and are described, inter alia, in U.S. Pat. Nos. 4,683,195 and 4,683,202 and in *PCR Protocols: A Guide to Methods and Applications*, ed. Innis et al., Academic Press, San Diego, 1990. Any well known method for nucleic acid amplification may be used in the practice of the present invention. The sequence of the heterologous DNA insert or flanking sequence from wheat 33391 event, ATCC accession No. PTA-2347 can be verified (and corrected if necessary) by amplifying such sequences from the event using primers derived from the sequences provided herein followed by standard methods of DNA sequencing of the PCR amplicon or of the cloned DNA molecule.

The amplicon produced by these methods may be detected by a plurality of techniques. Agarose gel electrophoresis and staining with ethidium bromide is a common well known method of detecting DNA amplicons. Another method is Genetic Bit Analysis (Nikiforov, et al. Nucleic Acid Res. 22:4167-4175, 1994) where an DNA oligonucleotide is designed which overlaps both the adjacent flanking genomic DNA sequence and the inserted DNA sequence. The oligonucleotide is immobilized in wells of a microtiter plate. Following PCR of the region of interest (using one primer in the inserted sequence and one in the adjacent flanking genomic sequence), a single-stranded PCR product can be hybridized to the immobilized oligonucleotide and serve as a template for a single base extension reaction using a DNA polymerase and labelled ddNTPs specific for the expected next base. Readout may be fluorescent or ELISA-based. A signal indicates presence of the insert/flanking sequence due to successful amplification, hybridization, and single base extension.

An additional method is the Pyrosequencing technique as described by Winge (Innov. Pharma. Tech. 00:18-24, 2000). In this method an oligonucleotide is designed that overlaps the adjacent genomic DNA and insert DNA junction. The oligonucleotide is hybridized to single-stranded PCR product from the region of interest (one primer in the inserted sequence and one in the flanking genomic sequence) and incubated in the presence of a DNA polymerase, ATP, sulfurylase, luciferase, apyrase, adenosine 5' phosphosulfate and luciferin. DNTPs are added individually and the incorporation results in a light signal which is measured. A light signal indicates the presence of the transgene/flanking sequence due to successful amplification, hybridization, and single or multi-base extension.

Fluorescence Polarization as described by Chen, et al., (Genome Res. 9:492-498, 1999) is a method that can be used



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to detect the amplicon of the present invention. Using this method an oligonucleotide is designed which overlaps the genomic flanking and inserted DNA junction. The oligonucleotide is hybridized to single-stranded PCR product from the region of interest (one primer in the inserted DNA and one in the flanking genomic DNA sequence) and incubated in the presence of a DNA polymerase and a fluorescent-labeled ddNTP. Single base extension results in incorporation of the ddNTP. Incorporation can be measured as a change in polarization using a fluorometer. A change in polarization indicates the presence of the transgene/flanking sequence due to successful amplification, hybridization, and single base extension.

Taqman® (PE Applied Biosystems, Foster City, Calif.) is described as a method of detecting and quantifying the presence of a DNA sequence and is fully understood in the instructions provided by the manufacturer. Briefly, a FRET oligonucleotide probe is designed which overlaps the genomic flanking and insert DNA junction. The FRET probe and PCR primers (one primer in the insert DNA sequence and one in the flanking genomic sequence) are cycled in the presence of a thermostable polymerase and dNTPs. Hybridization of the FRET probe results in cleavage and release of the fluorescent moiety away from the quenching moiety on the FRET probe. A fluorescent signal indicates the presence of the flanking/transgene sequence due to successful amplification and hybridization.

Molecular Beacons have been described for use in sequence detection as in Tyangi, et al. (Nature Biotech. 14:303-308, 1996) Briefly, a FRET oligonucleotide probe is designed that overlaps the flanking genomic and insert DNA junction. The unique structure of the FRET probe results in it containing secondary structure that keeps the fluorescent and quenching moieties in close proximity. The FRET probe and PCR primers (one primer in the insert DNA sequence and one in the flanking genomic sequence) are cycled in the presence of a thermostable polymerase and dNTPs. Following successful PCR amplification, hybridization of the FRET probe to the target sequence results in the removal of the probe secondary structure and spatial separation of the fluorescent and quenching moieties. A fluorescent signal results. A fluorescent signal indicates the presence of the flanking/transgene sequence due to successful amplification and hybridization.

The following examples are included to demonstrate examples of certain preferred embodiments of the invention. It should be appreciated by those of skill in the art that the techniques disclosed in the examples that follow represent approaches the inventors have found function well in the practice of the invention, and thus can be considered to constitute examples of preferred modes for its practice. However, those of skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments that are disclosed and still obtain a like or similar result without departing from the spirit and scope of the invention.

EXAMPLE 1

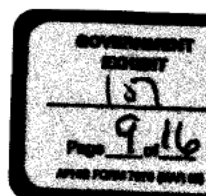
The transgenic wheat plants are generated by *Agrobacterium-mediated* transformation of wheat embryos by the method of Cheng et al. (Plant Physiol. 115:971-980, 1997) using the binary vectors of the present invention and a modification of the glyphosate selection conditions of Zhou et al. (Plant Cell Rep. 15:159-163, 1995). Other methods of wheat transformation are known to those skilled in the art of wheat transformation, such as, gene gun or particle bom-

bardment and can be used to insert the expression cassettes of the present invention into the genome of wheat cells. The T-DNA of pMON30139 (FIG. 3) contains two expression cassettes that collectively confer a high level of tolerance to glyphosate herbicide. The first transgene expression cassette comprises DNA sequences of the rice actin 1 promoter and intron (P-Os.Act1 and I-Os.Act1, U.S. Pat. No. 5,641,876, herein incorporated by reference in its entirety), operably connected to a DNA sequence encoding an *Arabidopsis thaliana* EPSPS chloroplast transit peptide (TS-At.EPSPS: CTP2, Klee et al., Mol. Gen. Genet. 210:47-442, 1987, herein incorporated by reference in its entirety), operably connected to a DNA sequence encoding a glyphosate resistant 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) isolated from *Agrobacterium tumefaciens* sp. strain CP4 (AGRTU.aroA gene, U.S. Pat. No. 5,633,435, herein incorporated by reference in its entirety), operably connected to a DNA sequence of a nopaline synthase transcriptional terminator (T-AGRTU.nos, Fraley et al., Proc. Natl. Acad. Sci. USA 80:4803-4807, 1983, herein incorporated by reference in its entirety). The second transgene expression cassette comprises a DNA sequence of a cauliflower mosaic virus 35S promoter containing a tandem duplication of the enhancer region (P-CaMV.35S:en, Kay et al., Science 236: 1299-1302, 1987; U.S. Pat. No. 5,164,316, herein incorporated by reference in its entirety), operably connected to a DNA sequence of a *Zea mays* Hsp70 intron (I-Zm.Hsp70, U.S. Pat. No. 5,424,412, herein incorporated by reference in its entirety), operably connected to a DNA sequence encoding an *Arabidopsis thaliana* EPSPS chloroplast transit peptide sequence (TS-At.EPSPS, Klee et al., Mol. Gen. Genet. 210:47-442, 1987), operably connected to a DNA sequence encoding a glyphosate resistant 5-enol-pyruvylshikimate-3-phosphate synthase (EPSPS) isolated from *Agrobacterium tumefaciens* sp. strain CP4 (AGRTU.aroA:CP4 gene, U.S. Pat. No. 5,633,435), operably connected to a DNA sequence of a nopaline synthase transcriptional terminator (T-AGRTU.nos, Fraley et al., Proc. Natl. Acad. Sci. USA 80:4803-4807, 1983).

pMON30167 (FIG. 1) is a single expression cassette identical to the first transgene expression cassette of pMON30139 as described above. pMON42411 (FIG. 2) is a single expression cassette identical to the second expression cassette of pMON30139 as described above.

After incubation of wheat cells with the *Agrobacterium* cells containing pMON42411, pMON30167 and pMON30139 constructs, glyphosate-tolerant transgenic wheat calli were selected on media containing 2 mM glyphosate for 1 week followed by transfer to a differentiation media with 0.1 mM glyphosate for 2 weeks and finally transfer to regeneration media with 0.02 mM glyphosate \pm 0.1 μ M aromatic amino acids.

Two hundred eight-four wheat events were produced from transformation with pMON42411, pMON30167 and pMON30139. These plants from pMON30139 and pMON30167 were sprayed once with 64 ounces/acre rate of glyphosate herbicide (Roundup Ultra™/acre) to select lines for vegetative and reproductive tolerance to glyphosate herbicide (Table 1). Plants from pMON42411 were sprayed twice with 64 ounces/acre rate of glyphosate herbicide. Selection of transformed wheat plants with the single expression cassettes of pMON42411 and pMON30167 resulted in a low percentage (1.4% and 3.2%, respectively) of wheat plants with both vegetative and reproductive tolerance. Only 3/134 plants from these constructs had acceptable levels of glyphosate herbicide tolerance. In contrast, transformed wheat plants containing the double expression



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cassette of pMON30139 produced a high percentage (16%) of plants with both vegetative and reproductive tolerance (24/150).

Wheat event 33391 (hence forth referred to as wheat plant 33391 or wheat 33391 and includes all plant parts and seed of this plant) was selected from the 150 transgenic wheat events produced from transformation with pMON30139. Twenty-four events were selected from this population that demonstrated improved vegetative and reproductive glyphosate tolerance. Further evaluation of these 24 events was conducted for agronomic performance and the presence of a single intact insertion. Wheat 33391 was selected from this population of events. The greenhouse and field evaluations of wheat 33391 and progeny derived from wheat 33391 indicated that this transgenic insertion confers glyphosate tolerance that exceeds commercial specifications of full vegetative and reproductive tolerance to 340 g glyphosate/acre (840 g glyphosate/hectare; 32 oz of Roundup Ultra/acre) with two-fold safety margin when applied at the 3-5 leaf stage.

TABLE 1

Comparison of efficacy of single and double expression cassettes for conferring glyphosate tolerance in wheat.			
pMON#	# events tested	# events with vegetative tolerance	# veg. tolerant events with reproductive tolerance
42411	71	26	1 (1.4%)
30167	63	4	2 (3.5%)
30139	150	104	24 (16%)

EXAMPLE 2

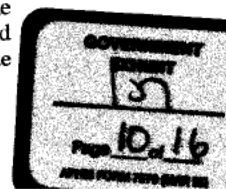
Isolation of the corresponding wheat genomic flanking sequence is possible by a variety of methods known to those skilled in the art (for example, using the ligated adapters and nested PCR as described in the Genome Walker™ kit, (CloneTech Laboratories, Inc, Palo Alto, Calif.). Genomic DNA from the wheat 33391 was isolated by CTAB purification method (Rogers et al., Plant Mol Biol 5:69-76, 1985). Reagents are available commercially (see, for example Sigma Chemical Co., St. Louis, Mo.). The genomic DNA libraries for amplification were prepared according to manufacturer instructions (Genome Walker™, CloneTech Laboratories, Inc, Palo Alto, Calif.). In separate reactions, genomic DNA was subjected to restriction enzyme digestion overnight at 37° C. with the following blunt-end endonucleases: DraI, EcoRV, PvuII, ScaI, and StuI (CloneTech Laboratories, Inc, Palo Alto, Calif.). The reaction mixtures were extracted with phenol:chloroform, the DNA was precipitated by the addition of ethanol to the aqueous phase, pelleted by centrifugation, then resuspended in Tris-EDTA buffer (10 mM Tris-HCl, pH 8.0, 1 mM EDTA). The purified blunt-ended genomic DNA fragments were then ligated to the Genome Walker™ adapters according to the manufacturer's protocol. After ligation of the adapters to the genomic DNA fragments, each reaction was heat treated (70° C. for 5 minutes) to terminate the reaction and then diluted 10-fold in Tris-EDTA buffer. One µl of each respective ligation was then amplified in a 50 µl reaction according to manufacturer's recommended protocol using an adapter-specific oligonucleotide (supplied by manufacturer) and a wheat 33391 transgene-specific oligonucleotide, such as SEQ ID NO:1, which anneals near the 5' end of the P-*Os*-*Act1*. The PCR mixture contained 1 µl of respective adapter-ligated library, 1 µl of 10 µM Genome Walker™

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adapter primer AP1 supplied by manufacturer (5'GTATATC-GACTCACTATAGGGC3', SEQ ID NO:11), 1 µl of 10 µM wheat 33391 transgene specific oligonucleotide (SEQ ID NO:1), 1 µl of 10 mM deoxyribonucleotides, 5 µl of 10×PCR buffer containing MgCl₂, 0.5 µl (2.5 units) of Taq DNA polymerase (Boehringer Mannheim Biochemicals, Indianapolis, Ind.), and H₂O to 50 µl. The PCR reactions were performed in a thermocycler using calculated temperature control and the following cycling conditions: 1 cycle of 94° C. for 1 minutes; 7 cycles of (94° C. for 2 seconds, 70° C. for 3 minutes); 37 cycles of (94° C. for 2 seconds, 65° C. for 3 minutes); 1 cycle of 65° C. for 10 minutes. One µl of each primary reaction was then amplified in a secondary amplification using a "nested" adapter-specific oligonucleotide (supplied by manufacturer) and a "nested" transgene-specific oligonucleotide such as SEQ ID NO:2, which anneals to P-*Os*.*Act1* upstream of the primer used in the primary reaction. The PCR mixture for secondary PCR contained 1 µl of respective primary PCR products, 1 µl of 10 µM Genome Walker™ nested adapter primer AP2 supplied by manufacturer (5'ACTATAGGGCAGCGTGGT3', SEQ ID NO:12), 1 µl of 10 µM wheat 33391 transgene-specific nested oligonucleotide (SEQ ID NO:2), 1 µl 10 mM deoxyribonucleotides, 5 µl of 10×PCR buffer containing MgCl₂, 0.5 µl (2.5 units) of Taq DNA polymerase (Boehringer Mannheim Biochemicals, Indianapolis, Ind.), and H₂O to 50 µl. The PCR reactions were again performed in a thermocycler using calculated temperature control and the following cycling conditions: 1 cycle of 94° C. for 1 minute; 7 cycles of (94° C. for 2 seconds, 70° C. for 3 minute; 31 cycles of (94° C. for 2 seconds, 65° C. for 3 minute); 1 cycle of 65° C. for 10 minute. PCR products, representing 5' regions that span the junction between the wheat 33391 transgenic insertion and the neighboring flanking genomic sequence were then purified by agarose gel electrophoresis followed by isolation from the agarose matrix using the QIAquick Gel Extraction Kit (catalog #28704, Qiagen Inc., Valencia, Calif.) and then directly cloned into the pGEM-T Easy vector (catalog #A1360, Promega, Madison, Wis.). The identity of the cloned PCR products was confirmed by DNA sequence analysis (ABI Prism™377, PE Biosystems, Foster City, Calif. and DNASTAR sequence analysis software, DNASTAR Inc., Madison, Wis.).

Similarly, the wheat 33391 3' flanking genomic DNA sequence was amplified and cloned using nested gene specific primers, such as SEQ ID NO:3, and SEQ ID NO:4, that anneal to the T-nos transcriptional terminator. Two T-nos transcriptional terminators are present in the wheat 33391 transgenic/genomic insertion, one internal in the construct and one at the 3' end of the construct adjacent to wheat genomic sequence. The PCR products produced in this reaction were sequenced and the DNA sequence that spans the junction between transgene and flanking genomic was distinguished from products of the internal T-nos by comparison to the known genetic element sequences of the pMON30139 construct.

Wheat genomic sequence flanking both sides of the transgene insertion site in the wheat genomic was determined for wheat 33391 by sequencing the Genome Walker™-derived amplification products and alignment to known transgene sequence. The sequence of a 399 base pairs (bp) segment around the insertion site was determined at the 5' end of the transgene insertion site. This segment consisted of 257 (bp) of wheat genomic sequence (nucleotide bases 1-257 of SEQ ID NO:5) and 93 bp of vector backbone sequence (nucleotide bases 258-350 of SEQ ID NO:5) and 49 bp of the 5' end of the rice *Act1* promoter (nucleotide



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bases 251-399 of SEQ ID NO:5). Similarly, DNA sequence was determined for a 431 bp segment flanking the 3' insertion junction (SEQ ID NO:6), beginning with 32 bp of the T-nos transcriptional terminator sequence (nucleotide bases 1-32 of SEQ ID NO:6), 68 bp of vector backbone sequence (nucleotide bases 33-100) and ending with 331 bp of wheat genomic sequence flanking the transgene insertion site (nucleotide bases 101-431 of SEQ ID NO:6). Identification of wheat 33391 was performed by PCR amplification of the transgene/genomic insertion region using one primer from transgene sequence and another primer from the wheat genomic flanking sequence. The 5' transgene/genomic insertion region was confirmed by PCR amplification of a DNA amplicon to be unique to wheat 33391. This identification was demonstrated by a PCR amplicon generated by primer 5 (SEQ ID NO:7) and primer 6 (SEQ ID NO:8). Additional primer sequences can be synthesized using the DNA sequence shown in SEQ ID NO:5 that will generate amplicons of DNA length different than the amplicon generated by primer 5 and primer 6, but are still diagnostic for wheat 33391 and progeny thereof. It is within the ordinary skill in the art of a plant molecular biologist to select DNA primer sequences from SEQ ID NO:5 and develop stringent conditions for the production of an amplicon. Likewise, those skilled in the art can select DNA primer sequences from SEQ ID NO:6 that will generate amplicons diagnostic for wheat 33391. It is within the scope of this invention that DNA primer sequences derived from SEQ ID NO:5 and SEQ ID NO:6 are useful for the isolation of additional genomic DNA molecules from wheat 33391 plants, seeds and plant part by the methods disclosed herein or methods known in the art of plant molecular biologist. These additional wheat genomic DNA molecules can be isolated in a method that uses any portion of sufficient length of the DNA

sequence disclosed in SEQ ID NO:5 and SEQ ID NO:6 useful as a primer or probe. The additional wheat genomic DNA molecules can be used as molecular markers diagnostic for wheat 33391.

DNA sequences that span the junction region of the wheat 33391 genomic DNA and the insert DNA of pMON30139 contained within SEQ ID NO:5 and SEQ ID NO:6 can be used as probes in a hybridization reaction to identify DNA derived from wheat 33391. For example, a DNA molecule useful as a probe from SEQ ID NO:5 would comprise the nucleotide sequence occurring from position 245-270 or its complement; a DNA molecule useful as a probe from SEQ ID NO:6 would comprise the nucleotide sequence occurring from position 87-113 or its complement. Those skilled in the art can select nucleotide sequences shorter or longer in length than those afore described that span the junction region and are useful as specific DNA probes or primers for wheat 33391 under high stringency conditions.

The PCR reaction conditions (Table 2) and quality of the extracted wheat 33391 genomic DNA are confirmed by the production of an amplicon by primer 7 (SEQ ID NO:9) and primer 8 (SEQ ID NO:10) and representing an approximately 400 bp DNA fragment from the wheat acetyl CoA carboxylase gene (Acc), a single copy endogenous gene within the wheat genome. The controls for this analysis should include a positive control from wheat 33391, a negative control from a wheat plant that is not wheat 33391, and a negative control that contains no template wheat DNA as shown in Table 2. The assay for the wheat 33391 amplicon can be performed by using a Stratagene Robocycler, MJ Engine, Perkin-Elmer 9700, or Eppendorf Mastercycler Gradient thermocycler as shown in Table 3, or by methods and apparatus known to those skilled in the art.

TABLE 2

PCR procedure and reaction mixture for the confirmation of wheat 33391 5' transgene/genomic junction region.			
Step	Reagent	Amount	Comments
1	Nuclease-free water	add to final volume of 20 μ l	—
2	10x reaction buffer (with $MgCl_2$)	2.0 μ l	1x final concentration of buffer, 1.5 mM final concentration of $MgCl_2$
3	10 mM solution of dATP, dCTP, dGTP, and dTTP	0.4 μ l	200 μ M final concentration of each dNTP
4	Primer 5 (SEQ ID NO:7) (resuspended in 1x TE buffer or nuclease-free water to a concentration of 10 μ M)	0.4 μ l	0.2 μ M final concentration
5	Primer 6 (SEQ ID NO:8) (resuspended in 1x TE buffer or nuclease-free water to a concentration of 10 μ M)	0.4 μ l	0.2 μ M final concentration
6	Primer 7 (SEQ ID NO:9) (resuspended in 1x TE buffer or nuclease-free water to a concentration of 10 μ M)	0.2 μ l	0.1 μ M final concentration
7	Primer 8 (SEQ ID NO:10) (resuspended in 1x TE buffer or nuclease-free water to a concentration of 10 μ M)	0.2 μ l	0.1 μ M final concentration
8	RNase, DNase free (500 ng/ μ l)	0.1 μ l	50 ng/reaction



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TABLE 2-continued

PCR procedure and reaction mixture for the confirmation of wheat 33391 5' transgene/genomic junction region.		
Step	Reagent	Amount
9	REDTaq DNA polymerase (1 unit/ μ l)	1.0 μ l (recommended to switch pipets prior to next step)
10	Extracted DNA (template): Samples to be analyzed	
	individual leaves	10-200 ng of genomic DNA
	pooled leaves (maximum of 50 leaves/pool)	200 ng of genomic DNA
	Negative control	50 ng of wheat genomic DNA (not wheat 33391)
	Negative control	no template DNA
	Positive control	50 ng of 33391 genomic DNA

TABLE 3

Suggested PCR parameters for different thermocyclers	
Gently mix and, if needed (no hot top on thermocycler), add 1-2 drops of mineral oil on top of each reaction.	
Proceed with the PCR in a Stratagene Robocycler, MJ Engine, Perkin-Elmer 9700, or Eppendorf Mastercycler Gradient thermocycler using the following cycling parameters.	
Cycle No.	Settings: Stratagene Robocycler
1	94° C. 3 minutes
38	94° C. 1 minute
	63° C. 1 minute
	72° C. 1 minute and 30 seconds
1	72° C. 10 minutes
Cycle No.	Settings: MJ Engine or Perkin-Elmer 9700
1	94° C. 3 minutes
38	94° C. 10 seconds
	63° C. 30 seconds
	72° C. 1 minute
1	72° C. 10 minutes
Cycle No.	Settings: Eppendorf Mastercycler Gradient
1	94° C. 3 minutes
38	94° C. 15 seconds
	63° C. 15 seconds
	72° C. 1 minute
1	72° C. 10 minutes

Note:

The MJ Engine or Eppendorf Mastercycler Gradient thermocycler should be run in the calculated mode. Run the Perkin-Elmer 9700 thermocycler with the ramp speed set at maximum.

EXAMPLE 3

The expression of the glyphosate resistant EPSPS protein (CP4 EPSPS) from aroA:CP4 gene can be detected by immunological methods (Rogan et al., Food Control 10:407-414, 1999, herein incorporated by reference in its entirety) from plant tissue extracts. Immunological methods such as western blots, strip tests, and enzyme linked immunosorbent assays (ELISA) have been developed to specifically detect the protein expressed from the aroA:CP4 gene contained in plant expression vectors transformed into plants. Reagents that include the polyclonal and monoclonal antibodies specific for the CP4 EPSPS are commercially available from Strategic Diagnostics (Newark, Del.). CP4 EPSPS can be

20 detected from protein extracts of wheat 33391 plants, plant parts and seeds by immunological methods that include ELISA.

An ELISA procedure that uses 100 ng of monoclonal anti-CP4 EPSPS antibody diluted in 100 μ l of 0.05 M carbonate-bicarbonate buffer pH 9.6 is absorbed to the well of a microtiter plate overnight at 4° C. The well is washed with phosphate buffered saline 0.05% Tween-20, pH 7.4 (PBS-T). The tissue is homogenized in phosphate buffered saline with a mortar and pestle or other suitable tissue grinder. The homogenate is added to the well of the microtiter plate and incubated for about 2 hours at 37° C. The well is washed three times with PBS-T. In one method, a secondary antibody, a purified rabbit anti-CP4 EPSPS is diluted to a sufficient level to provide specific binding to the CP4-EPSPS protein and incubated at 37° C. for about 1 hour. In a second method, a secondary antibody, a goat anti-CP4 EPSPS is used. A biotin-conjugated Mab anti-rabbit IgG or anti-goat IgG (Sigma Corp, St Louis Mo.) is added to the well (1:40,000 dilution in PBS) and incubated at 37° C. for 30 minutes. The well is washed three times with PBS-T. NeutrAvidin conjugated Horse radish peroxidase is diluted 1:10,000 using StabilZyme HRP-stabilizer (Stratagene, La Jolla, Calif.) and incubated at 37° C. for 15 minutes. The well is washed three times with PBS-T. The TMB substrate (Kirkegaard and Perry, Gaithersburg, Md.) is added for 10 minutes, then reaction quenched using 3 M phosphoric acid. The well is read with a microtiter plate reader at 450 nm using a reference wavelength of 650 nm. This method is an example of an ELISA suitable for detection of CP4 EPSPS and is not intended to be the only ELISA method that can be used to detect CP4 EPSPS, those skilled in the art of ELISA will know that variations to the method can be designed to provide a detection assay specific and sufficiently sensitive to detect CP4 EPSPS in a plant tissue extract.

ELISA of field grown forage of wheat event 33391 contain a mean level of 58.2 \pm 8.4 μ g/g, with a range of 45.5 to 72.4 μ g/g, CP4 EPSPS protein on a fresh weight tissue (fwt) basis, while the non-transgenic control forage had no detectable level of the CP4 EPSPS protein above the ELISA method's limit of detection at 0.9 μ g/g fw. Wheat event 33391 grain tissues contain a mean level of 12.6 \pm 2.5 μ g/g, with a range of 9.5 to 17.6 μ g/g, CP4 EPSPS protein on a fresh weight tissue (fwt) basis, while the non-transgenic control forage had no detectable level of the CP4 EPSPS protein above the ELISA method's limit of detection at 0.1 μ g/g fw. ELISA or other immunological methods for detect-



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17

ing CP4 EPSPS can be used as a diagnostic test for wheat 33391, when wheat 33391 progeny are the only USDA (United States Department of Agriculture) registered glyphosate tolerant wheat that expresses the CP4 EPSPS protein.

A deposit of the Monsanto Company, wheat 33391 disclosed above and recited in the appended claims has been made under the Budapest Treaty with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Va. 20110. The ATCC accession number is PTA-2347. The deposit will be maintained in the depository for a period of 30 years, or 5 years after the last request, or for the

18

effective life of the patent, whichever is longer, and will be replaced as necessary during that period.

Having illustrated and described the principles of the present invention, it should be apparent to persons skilled in the art that the invention can be modified in arrangement and detail without departing from such principles. We claim all modifications that are within the spirit and scope of the appended claims.

All publications and published patent documents cited in this specification are incorporated herein by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

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19

We claim:

1. A method of improving glyphosate tolerance in a wheat plant comprising:

- (1) constructing a DNA construct comprising a first and a second expression cassette, wherein said first expression cassette in operable linkage comprises (i) a rice actin 1 promoter; (ii) a rice actin 1 intron; (iii) a chloroplast transit peptide encoding DNA molecule; (iv) a glyphosate tolerant EPSPS encoding DNA molecule; and (v) a transcriptional terminator DNA molecule; and said second expression cassette comprising in operable linkage (a) a CaMV 35S promoter; (b) a Hsp70 intron; (c) a chloroplast transit peptide encoding DNA molecule; (d) a glyphosate tolerant EPSPS encoding DNA molecule; and (e) a transcriptional terminator DNA molecule; and
- (2) transforming a wheat cell with said DNA construct; and
- (3) regenerating said wheat cell into a wheat plant or wheat plants; and
- (4) treating said wheat plants with an effective dose of glyphosate; and

(5) selecting fertile wheat plants that are vegetative and reproductive tolerant to glyphosate.

2. A fertile glyphosate tolerant wheat plant produced by the method of claim 1.

3. A seed of the glyphosate tolerant wheat plant of claim 2, wherein said seed comprises the construct of claim 1.

4. A glyphosate tolerant wheat plant comprising a DNA construct comprising a first and a second expression cassette, wherein said first expression cassette in operable linkage comprises (i) a rice actin 1 promoter; (ii) a rice actin 1 intron; (iii) a chloroplast transit peptide encoding DNA molecule; (iv) a glyphosate tolerant EPSPS encoding DNA molecule; and (v) a transcriptional terminator DNA molecule; and said second expression cassette comprising in operable linkage (a) a CaMV 35S promoter; (b) a Hsp70 intron; (c) a chloroplast transit peptide encoding DNA molecule; (d) a glyphosate tolerant EPSPS encoding DNA molecule; and (e) a transcriptional terminator DNA molecule.

5. A seed of the glyphosate tolerant wheat plant of claim 4, wherein said seed comprises the DNA construct.

* * * * *



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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,268,274 B2
APPLICATION NO. : 10/727423
DATED : September 11, 2007
INVENTOR(S) : Guilan Chen, Catherine M. Hironaka and Hua-ping Zhou

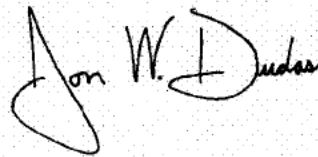
Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- Column 21, claim 1, line 34 — delete “chioroplast” and insert --chloroplast--.

Signed and Sealed this

Eighteenth Day of December, 2007



JON W. DUDAS

Director of the United States Patent and Trademark Office



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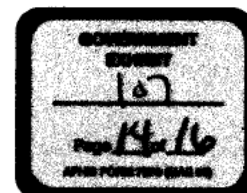
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From: Juarez, Bernadette R - APHIS
Sent: Wednesday, July 03, 2013 9:13 AM
To: APHIS-IES RR Wheat
Subject: FW: Monsanto's review of seed purity RE MON71800
Attachments: Science summary Japan final.pdf

Everyone –

Please see attached. This summary provides background information on possible comingling methods.

It is a quick read, please take a look.

B.

Bernadette Juarez, Deputy Director
Investigative and Enforcement Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
4700 River Road
Unit 85 (Room 6B-03B)
Riverdale, Maryland 20737
(301) 851-2735
(301) 734-4328 (facsimile)
bernadette.r.juarez@aphis.usda.gov

From: Chou, Fan-Li FAS [<mailto:Fan-Li.Chou@fas.usda.gov>]
Sent: Wednesday, July 03, 2013 12:10 PM
To: Schechtman, Michael; Pitchford, John - GIPSA; Firko, Michael J - APHIS; Juarez, Bernadette R - APHIS
Cc: Holtzman, Max - OSEC; Vetter, Darci - OSEC; Porter, Ed FAS; Jones, Elizabeth FAS
Subject: Monsanto's review of seed purity RE MON71800

Hello all,

(b) (5)

Looking forward to your thoughts.
Fan-Li



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(via e-mail) on July 03, 2013

OR120018_BR_003258

Fan-Li Chou, PhD
Senior Advisor, Science & Trade

Tel: 202-690-3335
Fax: 202-690-3316
Email: Fan-Li.Chou@fas.usda.gov

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Work Schedule - Monday thru Thursday

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Scientific review supporting MON71800 wheat event limited to single field location

Comprehensive assessment of event safety, seed
stocks, and grain

Monsanto Company

7/1/2013



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OR120018_BR_003262

Evidence demonstrates that USDA's announced finding of CP4 Event 71800 is limited to a single field on a single farm in Oregon

Absence of CP4 Event 71800 in widespread seed testing confirms confidence there is no CP4 Event 71800 in the US commercial wheat supply

Overview:

The following paper addresses three major topics related to the recent finding of RR wheat. Part I reviews the established safety of the wheat CP4 event. Part II reviews information regarding the presence of the CP4 event in the environment and demonstrates that all evidence indicates that the finding announced by USDA is limited to one field on one farm in the state of Oregon. Finally, Part III reviews information regarding the testing of the CP4 event in commercial seed, demonstrating it is neither present in the seed supply or in commercial grain. In summary, the weight of the evidence herein supports that the MON71800 CP4 event is not in seed stock or grain found in commerce, but limited to a single isolated field.

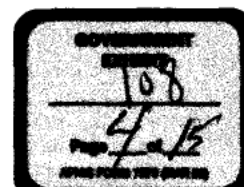
Background:

Monsanto has developed biotechnology-derived crop products that provide herbicide tolerance, predominantly based on a naturally occurring form of the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein, an enzyme found in most plants and microbes. This glyphosate-tolerant EPSPS protein isolated from an *Agrobacterium* sp., CP4 EPSPS, has been introduced into crops to provide tolerance to glyphosate, the active ingredient in the Roundup® family of agricultural herbicides. Crops tolerant to Roundup herbicides are marketed around the world as Roundup Ready®.

In the U.S., Roundup Ready crops based on the CP4 EPSPS protein were first planted commercially in 1996 with the introduction of Roundup Ready soybeans. Since then multiple herbicide-tolerant crops, based on the CP4 EPSPS protein have been commercialized, including: Roundup Ready alfalfa, Roundup Ready canola (GT73), Roundup Ready corn (NK 603), Roundup Ready cotton (MON 1445 and MON 88913), Roundup Ready soybean (MON 4032) and Roundup Ready 2 Yield soybean (MON 89788) and Roundup Ready sugarbeet (H7-1).

The aggregate commercial experience as of 2012 amounts to over 3.7 billion acres of biotechnology-derived crops planted in the world (ISAAA, 2012), with Roundup Ready crops a significant portion of this acreage.

® Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.



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OR120018_BR_003264

RR wheat was under development at Monsanto from the late 90's through 2005 when commercial development and all related activities were discontinued. On May 29, 2013 the USDA announced that there had been a finding of RR wheat volunteers on a single field on a single Oregon farm. The volunteer plants contained event MON71800 which had been under development by Monsanto. The farmer reported planting a variety seed mix of the varieties ROD and WB528 in the fall of 2011. The seed blend which was planted in this field was also planted in two other fields on the same farm which, as determined by the USDA testing, showed no presence of the MON71800 event. Those facts demonstrated the isolated nature of the incident, and importantly, that the MON71800 was not present in the original seed stock planted by the grower.

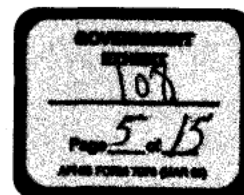
Part I: The safety of RR crops, including RR wheat

An extensive set of studies have been conducted to show the safety of RR crops. They include:

Bioinformatic analysis of CP4 EPSPS: The EPSPS family of enzymes which are involved in the biosynthesis of aromatic amino acids is ubiquitous to plants and microorganisms but is absent in mammals, fish, birds, reptiles and insects. Bioinformatics analysis of CP4 EPSPS shows that while EPSPS proteins have divergent amino acid sequences, all forms have secondary and tertiary related structures. Additional analysis showed that CP4 EPSPS does not share homology to known toxic and pharmacologically-active proteins.

Studies of isolated CP4 EPSPS protein: Simulated mammalian gastric and intestinal digestive fluid studies show that this protein is degraded rapidly and it has been established that proteins that behave like this have a low likelihood to produce toxic or pharmacological effects. An acute oral toxicity study confirmed that no treatment related adverse effects are observed on ingestion of CP4 EPSPS.

Studies of CP4 EPSPS containing plants: It has been established by OECD, WHO and FAO, and globally accepted, that compositional comparison to a traditional crop is a cornerstone in the scientific process of establishing food, feed and environmental safety. All Roundup Ready crops including RR wheat have undergone extensive compositional analysis, including assessment of proximates, fatty acids, amino acids, and nutritionally relevant minerals, vitamins, and secondary metabolites, including those with anti-nutritional properties. All Roundup Ready crops' compositional analyses have demonstrated compositional equivalence to their traditional counterparts. As such, insertion of the CP4 EPSPS gene and expression of the CP4 EPSPS protein have no detectable effect on Roundup Ready crop composition.



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Animal feeding studies of CP4 EPSPS: Animal feeding studies have been performed on each Roundup Ready crop's agricultural commodities grown under field conditions to establish nutritional equivalence of Roundup Ready crops to traditional crop counterparts. CP4 EPSPS-containing agricultural commodities have been fed in diet to broilers, beef cattle, dairy cows, sheep, swine, and rats. The independent researchers conducting these feeding studies have all concluded that Roundup Ready crops are as nutritious and safe as the traditional counterparts. Prior to commercial introduction, some Roundup Ready crop products (including RR wheat) have been fed in animal feeding studies to support market acceptance at the anticipated commercial introduction. Roundup Ready wheat was fed in diet, at inclusion rates up to 85%, to broilers and swine throughout the animal rearing phases. In both studies, the independent researchers concluded that Roundup Ready wheat was nutritionally equivalent to, and as safe and efficacious as, its traditional counterpart.

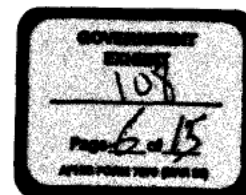
Since 1986, the United States government has regulated biotechnology-derived crops pursuant to the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework). The Coordinated Framework defines the regulatory roles and authorities for the three major U.S. agencies involved in regulating biotech crops: USDA's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). The FDA regulates biotech crops under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA) under a consultation process and is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those that are biotechnology-derived. Although RR wheat was never commercialized it did complete all studies and completed FDA consultation in 2004.

In conclusion, Roundup Ready crops, including RR wheat, expressing the CP4 EPSPS protein have been well characterized. Globally, regulatory agencies have consistently concluded that CP4 EPSPS-based Roundup Ready crops are as nutritious and safe as their traditional counterparts. FDA successfully completed its review of the safety of RR wheat event MON71800.

Part II: No evidence that CP4 wheat event is present in the environment: Finding is limited to a single field on a single farm in Oregon

Lack of any claims of glyphosate tolerant wheat since the last testing of the CP4 event in Oregon over 12 years ago.

Monsanto's Roundup Chemistry (glyphosate) claims database shows that there have been no unusual reports of wheat volunteers surviving glyphosate application since the company



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terminated the RR wheat program and completed the last field trial in 2005. The detection of RR wheat in a single field in Oregon nearly a decade later after any field trials anywhere in the US is a unique and isolated incident.

Information in the following section establishes that the RR wheat field trials are not the source of this event in the environment.

Wheat viability and rigorous stewardship practices

The discovery of RR wheat cannot be logically explained as deriving from seed or pollen remaining in the field from trials conducted about a decade ago as part of the RR wheat project (late 90's to 2005). There are 3 lines of evidence that establish this:

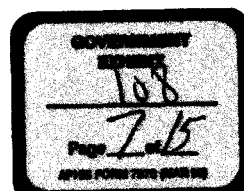
- 1) **Wheat seed viability and pollen flow in the environment:** Wheat seed is viable for only a relatively short period of time in the environment, certainly not a decade.

A) Wheat seed viability (1,2):

Under normal environmental conditions, wheat seed only remains viable in the environment for a couple of years. There have been numerous research studies conducted to validate this statement. In 2003, a peer-review journal article was published in *Weed Technology* titled *Review of Volunteer Wheat (*Triticum aestivum*) Seedling Emergence and Seed Longevity in Soil*. The authors reviewed literature on volunteer wheat seedling emergence and seed longevity in soil. They stated that "Data from classical burial studies suggested that wheat seeds were short-lived in soil, persisting less than 1 yr." They also reported that in field conditions, volunteer wheat seedling emergence may be somewhat longer (up to 2 years) depending on three factors: 1) cereal grains require an after-ripening period before seeds can germinate (0-7mo), 2) burial studies seed densities were in excess of natural occurrence in the soil seedbank perhaps leading to a higher level of microbial decomposition, and 3) precipitation levels are typically higher at the classical burial locations than in semiarid regions. Despite these factors, this research review supports the fact that wheat seed only remains viable for a couple of years. This article also reported that tillage had an impact on volunteer emergence with "fivefold more seedlings emerged in no-till than with tillage with a sweep plow." This is significant in that a common practice in Oregon is to use a chemical fallow (no-till) system for conserving moisture between crops. Nielson, et. al., reported their findings in Western Canada in *Weed Science* in 2009. Their findings were that seed viability declined exponentially over time.

B) Pollen flow (3-11):

Wheat is a predominantly self-pollinated crop, but it is widely recognized that low levels of cross-pollination and gene flow can occur within this species. However, the ability to



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control gene flow in wheat through the use of spatial separation is also well documented. There is a considerable amount of public research demonstrating that the potential for pollen-mediated gene flow (PMGF) is generally less than one percent at a distance of 10 meters separation between pollen donor and receptor. Out-crossing detection declines rapidly with distance from the pollen donor, with distances of 30-40 meters consistently resulting in measured PMGF levels at or below 0.01%.

Wheat pollen is also only viable for a relatively short period of time, 30-60 minutes under optimal environmental conditions.

Factors such as relative humidity, wind direction, temperature, time of flowering, and genetic disposition of a variety to out-crossing are also important as they can mitigate or enhance the PMGF rates. Wheat produces relatively low volumes of pollen, less than 10% of that produced by rye and less than 3% of that produced by corn. Due to the hexaploid nature of bread wheat, the pollen grains themselves are also heavy and generally fall very close to the pollen donor. Wheat pollen is wind dispersed and there are no known insect vectors for wheat pollination. Varietal or genetic differences for out-crossing propensity have also been documented, primarily influenced by maturity or time of flowering and flower morphology.

In order to avoid the possibility of pollen-mediated transfer of the MON71800 event to other wheat plants, strict stewardship measures were implemented (detailed below), including the use of buffer zones, the destruction of the buffer zones at trial completion and monitoring for volunteers in the buffer zone.

- 2) Field stewardship program: Strict field stewardship protocols were followed for all field tested material to ensure that viable plant material was contained in the test sites.

A) Shipping (movement of seed):

- All material was identified by a tag inside and outside the bag and material was double contained with each layer being able to prevent any loss of seed.
- All material was placed under lock and key at all cooperator locations.
- Material was handled in a separate area from the normal wheat program.
- All material was transported to the field location in the original container.

B) Planting and Harvesting:

- There were isolation borders or buffers around field trials to prevent contamination. Isolation buffers in all trials were a minimum of 20 feet. The buffer had to be either bare ground or could contain a sexually incompatible plant.
- All wheat seed taken to the field was planted in the fields, all equipment was cleaned within the plot area after planting to ensure no seed was left in the



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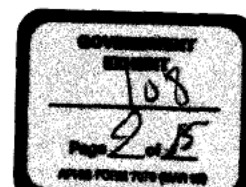
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equipment, and all excess seed and containers were burned and/or buried in the plot area.

- All isolation and volunteer monitoring complied with the USDA performance standards.
 - All harvesting equipment was cleaned in the field and all excess harvested wheat seed was buried or burned in the field.
 - In addition to the required monitoring, Monsanto enlisted a third party to monitor planting and harvesting of field trials conducted after 2000.
- C) Program discontinuation: As the RR wheat program was being terminated starting in 2004, thorough steps were taken to ensure that all material in the hands of cooperators was either destroyed or collected.
- Remnant seed from all cooperative spring wheat programs was shipped to the USDA National Center for Genetic Resource Preservation in Fort Collins, Colorado (All Winter wheat varieties from private and public breeders where trait introgression was conducted, were never sent back to the cooperators- they were retained by Monsanto.).
 - Any material that was shipped was packaged, handled and transported in accordance with the above guidelines.
 - Each field cooperator signed a letter of verification that any remaining material had been shipped to the USDA and no material remained in their possession. The verification document was signed by the cooperator, their manager and the manager's manager.
 - All monitoring for volunteer wheat continued for at least two years or until no volunteers were observed for one year, whichever was longer.
 - Monsanto has retained the documentation of this discontinuation effort, including documentation from the cooperators that remnant material was handled as outlined above and from the USDA that the seed was stored and ultimately destroyed in 2012.

- 3) Field location in Oregon: The farm location of this detection was never a location for any RR wheat field trials.

In summary, given the combination of evidence above which includes the fact that wheat seed does not remain viable in the environment for a long period of time (certainly not the 12 years between the last field testing in Oregon and this finding), the limited potential for pollen mediated transfer of the event to other plants, the stringent stewardship efforts that were demonstrated for all field testing, and most importantly the fact that the location of the finding of the MON71800 CP4 volunteers was never a field test location for MON71800, it is inconceivable that these volunteers found in one field originated from material tested in the



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field during the RR wheat development program and show that the potential for any RR wheat being in the environment resulting from this work is extremely remote.

The following Part will cite testing results from multiple sources (Monsanto, Washington State University, the USDA) demonstrating that the commercial seed supply is not a possible source of this event and that commercial grain does not contain the event.

Given the safety, length of time under consideration, and evidence that; 1. Controls to prevent exposure to the environment have been successful and complete and 2. No evidence in addition to the single finding in a single field exists that that CP4 wheat event is present in the environment, it is most logical that an examination of seeds intended for and used in planting is used to validate that there is no CP4 Event MON 71800 in the US commercial wheat supply.

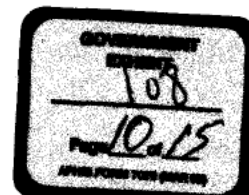
Part III: Confirmed absence of CP4 wheat event MON71800 in U.S. seed supply underscores that no CP4 is in U.S. commercial grain

Extensive testing of commercial seed has been conducted by the USDA, Monsanto and Washington State University (WSU). Testing by Monsanto and Washington State University includes more than 75 wheat varieties representing 6 different classes (Soft White Winter and Spring, Club, Hard White, Hard Red Winter and Spring) planted in the Pacific Northwest. Importantly, the soft white class varieties tested represents 97 percent of the Oregon soft white wheat acres for which varieties were reported in 2011. The results of these testing programs indicate that there has been no detection of the MON71800 CP4 event in these commercial wheat seed stocks. This eliminates seed stocks and breeding program contamination as the source of the wheat volunteers on this one farm.

Monsanto:

Monsanto conducted analytical testing using a validated TaqMan® PCR method, designed to detect the specific CP4 event 71800 with accuracy and precision. A total of 58 wheat varieties were tested to demonstrate that those seed varieties were at least 99.5% pure with 95% confidence, and zero detection of the CP4 event MON71800. Sampling and testing was performed in accordance with SeedCalc8, which is distributed by the International Seed Testing Association and is used to determine sample size requirements for various seed/grain purity testing questions.

The TaqMan®PCR testing was performed in a laboratory that is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of laboratory quality management system.



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In addition, this laboratory participates in the USDA/GIPSA Proficiency Program. Through the USDA/GIPSA Proficiency Program, USDA seeks to improve the overall performance of testing for biotechnology-derived grains and oil seeds. The USDA/GIPSA Proficiency Program helps organizations identify areas of concern and take corrective actions to improve testing accuracy, capability and reliability.

Monsanto's testing, using the validated method described above, shows that testing was completed on approximately 35,000 samples covering 58 wheat varieties. Some key statistics regarding these 58 wheat varieties are (Figure 1):

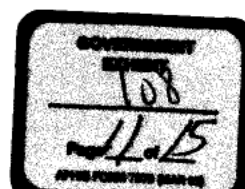
- Two of the 58 varieties were ROD and WB528 which are the 2 varieties the farmer blended to plant on his field. Both of these varieties belong to the soft white winter class of wheat.
- Apart from the Soft White class (winter and spring) the tested varieties also include varieties from the Hard Red Spring and Hard Red Winter classes.
- The geographical area represented by the 58 wheat varieties extends beyond the bi-state region of Oregon and Washington to Idaho and Montana.
- Thirty two (32) of these varieties are in the class of Soft White and in total represent more than 80 percent of all the acres of soft white wheat seed varieties grown in the bi-state region of Oregon and Washington for 2011.
- Fifteen (15) of these varieties are in the class of Hard Red Spring with the set representing not only varieties grown in the bi-state region but also Montana.
- Eleven (11) of these varieties are in the class of Hard Red Winter with the set also representing not only varieties grown in the bi-state region but also Montana.

In summary, Monsanto tested seed samples representing a broad geographical area and extends across different wheat classes. Additionally, Monsanto test results, using the precise event-specific method, show no detectable presence of the CP4 event in any commercial seed stocks. The absence of the MON71800 event in seed stocks means that MON71800 cannot be present in commercial grain, as the grain is the end product of seed stock planted in this area that predominantly utilizes certified seed.

Washington State University (WSU):

A comprehensive glyphosate field screening program was initiated by WSU soon after the reported detection of MON71800 in Oregon. The testing protocol utilized existing plant populations in field studies and seed increases. In seed increase fields, an area representing a plant population that would produce approximately 3,000,000 wheat heads per acre was tested. The protocol established was as follows:

1. A labelled rate of glyphosate herbicide was applied to the selected field area.
2. Any plants surviving 14 days after the initial application were sprayed a second time.
3. Plants surviving after two sprays would be collected and advanced to molecular testing.



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Using the above methodology, Washington State University reported as follows:

- The University reported in June that it had "screened public and private varieties representing 90 percent of Washington's soft white wheat crop and found no evidence of glyphosate-resistant wheat."
- WSU also "screened nearly three-fourths of the less heavily planted spring wheat varieties, with similar results."

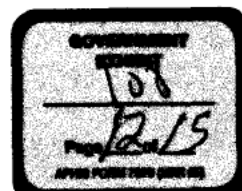
WSU said the process "has involved 60 varieties, 1,900 advanced breeding lines and more than 20,000 individual plots from WSU programs" to date. Testing included 26 commercially grown varieties from both the WSU and Oregon State University and covered many classes of wheat including Soft White Winter and Spring, Club, Hard White and Hard Red Winter and Spring.

In summary, Washington State University (WSU) data also represents a broad geographical area and extends across multiple wheat classes. WSU test results, using a rigorous screening methodology, show no detectable presence of the MON71800 CP4 event in commercial and pre-commercial seed stocks. Once again, the absence of the MON71800 event in seed stocks demonstrates the lack of presence in commercial grain as the grain would be the end product of seed stock planted in this area that predominantly utilizes certified seed.

USDA:

Two different USDA laboratories tested the volunteer wheat plants that survived treatment with glyphosate and used an event-specific PCR methodology that Monsanto provided to USDA. Samples of plants that survived glyphosate treatment tested positive in the PCR tests for the 35S promoter, the NOS terminator, and Monsanto Event 71800. USDA confirmed that the plant material tested was Event 71800 through DNA sequencing. USDA sent DNA derived from the event-specific PCR test to an outside laboratory to sequence the DNA. The outside laboratory provided USDA with the DNA sequence, and USDA scientists compared that sequence with DNA sequence information provided by Monsanto about Event 71800 and public information about the wheat genome.

USDA investigators collected seed samples from the entity that sold the seed to and purchased the harvested grain from the producer. USDA tested these seed samples initially using the 35S quantitative PCR assay. Thus far USDA has conducted over 100 tests involving, 8 samples of seed and 4 samples of grain (including the 2012 grain harvest from the farmer with the subject field, using 35S quantitative PCR assay with a 0.03 percent limit of detection (1 in approximately 3,333 kernels based on average kernel weight). USDA tested 9 pools from each of the 12 samples to achieve a 0.003 percent limit of detection (1 in approximately 30,000 kernels). A MON71800 event specific PCR assay would be conducted on any sample that tests positive for



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35S. **No samples have tested positive.** USDA used the 35S assay for several reasons: (1) it is a publicly available, widely used assay (developed in Japan); (2) USDA could conclusively test at the 0.03 percent limit of detection, and provide greater sensitivity by using multiple pools, and; (3) USDA could generate more results faster using this method. USDA also provided Japan with source information for obtaining and reviewing the 35S PCR test.

The USDA confirmed in a statement released by its BRS unit that, based on their own testing and the information they have gathered, they could “confirm that testing associated with the investigation so far has been negative and that we have no information that GE wheat is in commerce.” This includes:

- Testing of the seed (Rod and WestBred 528 varieties) originally planted on the 123-acre Oregon farm in 2011.
- Testing grain harvested on the field in 2012.

We understand that the USDA investigators are “continuing to conduct interviews with approximately 200 area growers”, and Secretary Vilsack has commented that numerous tests in adjoining fields suggest that the reported detection has been limited to this particular field.

The USDA has confirmed that “all of these samples of seed and grain tested negative for the presence of GE material.”

The extensive set of analyses and conclusive tests results from the USDA, Monsanto, and Washington State University, continue to demonstrate that the commercial seed supply and grain harvested in the Pacific Northwest region does not contain the CP4 event 71800. These data further underscore the conclusion that the detection of RR wheat volunteers is an isolated case.

The weight of evidence presented in this paper demonstrate that not only is this event limited to one field on one farm in the state of Oregon, but highlights that it is not in commerce. We encourage a risk proportionate and science based approach be deployed in light of the above analysis and information. Given the facts regarding safety and presence of CP4 Event 71800, it is clear that CP4 Event 71800 does not exist in the commercial grain supply. We believe that further testing of commercial grain should not be warranted.



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FIGURES

Figure 1

TESTING RESULTS ACROSS 4 WHEAT CLASSES									
VARIETY	POSITIVE RESULTS	VARIETY	POSITIVE RESULTS	VARIETY	POSITIVE RESULTS	VARIETY	POSITIVE RESULTS	VARIETY	POSITIVE RESULTS
AP 700 CL	0			WB 523	0			WB-JUNCTION	0
BRUNDAGE 96	0			WB 528	0			XERPHA	0
ELTAN	0			WB-1066CL	0				
GOETZE	0			WB-1070CL	0				
MADSEN	0			WB-1081CL+	0				
ORCF-101	0			WB6123	0				
ALPOWA	0			WB-1035CL+	0				
DIVA	0			WHIT	0				
BUCK PRONTO	0			SY TYRA	0			WB-FUZZON	0
CORSIN	0			SY605CL	0			WB-GUNNISON	0
DUCLAIR	0			VIDA	0			WB-ROCKLAND	0
CARTER	0			SY-WOLF	0				
JUDEE	0			WB ARROWHEAD	0				
KELDIN	0			WB OLIVIA	0				

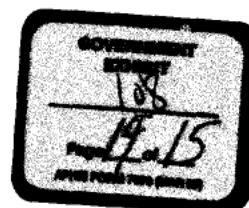
CITATIONS

Seed Viability References

- 1) Anderson, R. L. and G. Soper. 2003. Review of Volunteer Wheat (*Triticum aestivum*) Seedling Emergence and Seed Longevity in Soil. *Weed Technology*, 17:620-626.
- 2) Nielson, R. L., M. A. McPherson, J. T. O'Donovan, N. Harker, R. Y. Yang and L. M. Hall. 2009. Seed-Mediated Gene Flow in Wheat: Seed Bank Longevity in Western Canada. *Weed Science*, 57:124-132.

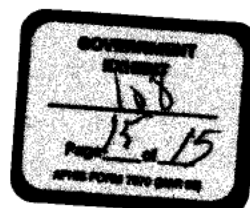
Pollen Flow References

- 3) Hucl, P. 1996. Outcrossing rates for 10 Canadian spring wheat cultivars. *Can. J. Plant Sci.* 76:423-427.
- 4) Martin, T. J. 1990. Outcrossing in twelve hard red winter cultivars. *Crop Sci.* 30:59-62.
- 5) Hucl, P. and M. Matus. 2001. Isolation distances for minimizing outcrossing in spring wheat. *Crop Sci.* 41:1348-1351
- 6) Griffin, W. B. 1987. Outcrossing in New Zealand wheats measured by occurrence of purple grain. *New Zealand J. Agric Res.* 30: 287-290.



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- 7) Loureiro, I. et al. Wheat pollen dispersal under semiarid field conditions: potential outcrossing with *Triticum aestivum* and *Triticum turgidum*. *Euphytica* (2007) 156:25-37.
- 8) Gaines et al. An Empirically Derived Model of Field-Scale Gene Flow in Winter Wheat. *Crop Sci.* (2007) 47:2308-2316.
- 9) Hucl, P. and M.A. Matus-Cadiz. Postharvest Survey of Spring Wheat Fields Initially Assessed for Gene Flow. *Crop Sci.* 50:1904-1907 (2010).
- 10) Matus-Cadiz, M.A., P. Hucl, M.J. Horak and L.K. Blomquist. *Crop Sci* 44:718-727 (2004).
- 11) Beckie, H.J. et al. Pollen-Mediated Gene Flow in Commercial Fields of Spring Wheat in Western Canada. *Crop Sci.* (2011) vol. 51.



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Declaration of (b) (6), (b) (7)(C)

I declare that my name is (b) (6), (b) (7)(C), I am over the age of eighteen and I am fully competent to make this declaration. I know each of the facts set forth herein to be true based on personal firsthand knowledge:

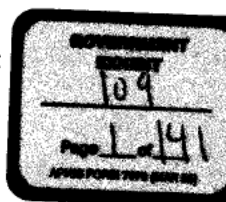
I am currently employed as an Investigator with the United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS), Investigative and Enforcement Services (IES). My employment with USDA, APHIS, IES began in May of 2007. My business address is USDA, APHIS, IES, 2150 Centre Avenue, Bldg. (b) (6), (b) (7)(C) Fort Collins, CO 80526. My office telephone number is (b) (6), (b) (7) and my cell phone number is (b) (6), (b) (7)

On 12/03/13 through 12/13/13, Sharon M. Talley, Ph.D., Biological Scientist, Western Compliance Assurance Branch USDA - APHIS – Biotechnology Regulatory Services (BRS), (Dr. Talley) and I travelled to Monsanto Company, 800 North Lindbergh Blvd., St. Louis, Missouri 63167, 314-694-1000.

Dr. Talley and I were at Monsanto to review field test books from (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) during the time of the MON71800 testing (b) (6), (b) (7)(C). Also during our visit to Monsanto, we obtained compliance reports of WestBreds' work with the MON71800 test plots.

During our trip to Monsanto in St. Louis, MO we requested documentation to verify statements from the Monsanto science report dated 7/1/13, titled; **Scientific review supporting MON71800 wheat event limited to single field location**. We also requested seed samples for additional analysis. Also requested was additional documents relating to the volunteer monitoring in MON71800 field trials.

On 01/10/14, I again requested the **Scientific review supporting MON71800 wheat event limited to single field location** and seed samples, from their seed stocks, for the "final developmental stage" material (and any genetic analysis or documentation that Monsanto



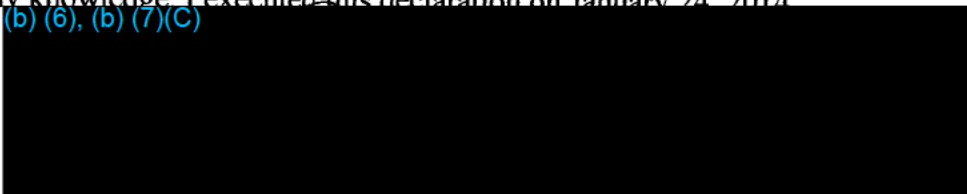
maintains on the same) for Express and Espresso to compare genetics with volunteers.
On 01/21/14, IES received many documents in reference to the **Scientific review supporting MON71800 wheat event limited to single field location**.

On 01/21/14 thru 01/24/14, I reviewed all of the **Scientific review supporting MON71800 wheat event limited to single field location** documents which we had received. From this review, it appears that the remaining MON71800 was disposed of in the manner prescribed.

I found nothing, which would lead me to connect these noncompliance issues to the contamination of the Oregon farmers' field where the MON71800 was discovered in 2013.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. I executed this declaration on January 24, 2014.

(b) (6), (b) (7)(C)



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Investigator

USDA-APHIS-IES



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MONSANTO COMPANY
TECHNOLOGY ALLIANCES TEAM
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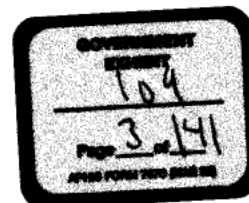
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MONSANTO



September 27, 2004

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

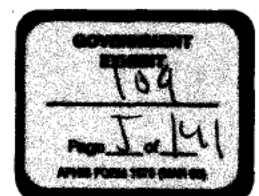
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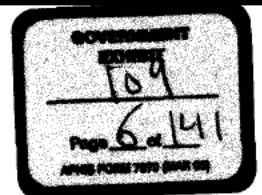
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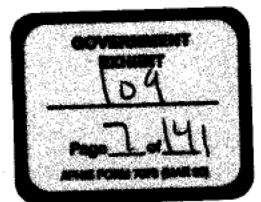
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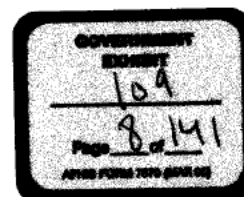
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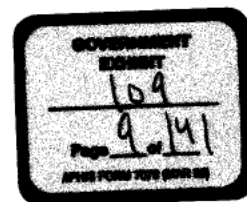


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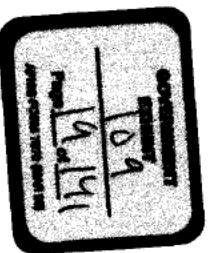
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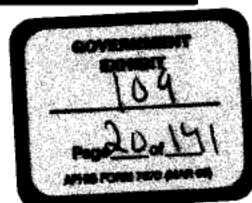
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July 18, 2003

(b)(4)



(b)(4)



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January 21, 2014

(b) (6), (b) (7)(C)

USDA Senior Investigator
APHIS Investigative and Enforcement Services

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

USDA Inquiry re: Wheat Detection on a Field in Oregon

Dear

I write on behalf of Monsanto in response to your email of January 10, 2014 seeking certain additional documents and seed samples. We have been pleased to cooperate in your inquiry over the past several months and thank you again for your courtesy and professionalism. Below, please find: (1) detailed responses to each of your recent requests; (2) a brief discussion regarding the status of your inquiry; and

(b) (4)

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Responses to January 10, 2014 Requests

The documents we are providing today supplement the hundreds of pages we previously produced during 2013. Many of the documents originate from files available for review during your witness interviews at Monsanto's facilities in St. Louis. As was true previously, these documents are Confidential Business Information ("CBI"), and have been stamped accordingly. Our CBI justification, set out in our letter of November 29, 2013, applies not only to all the documents previously provided, but also to those transmitted herewith. (For ease of reference, please find another copy of our November 29, 2013 letter attached hereto as Exhibit A.) We appreciate your careful efforts to comply with the APHIS's Guidelines for Handling CBI. See APHIS Policy Statement on the Protection of Privileged or Confidential Business Information, 50 Fed. Reg. 38,561 (Sept. 23, 1985) (establishing very detailed APHIS protocols for handling CBI documents).

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(b) (4), (b) (6), (b) (7)(C)

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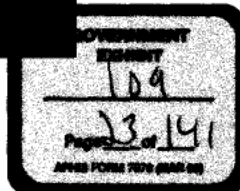
(b) (6), (b) (6)

USDA has also requested available samples of (b) (4). We are happy to provide samples of seed Monsanto possesses and will do so soon, along with detailed information regarding the nature, origin and chain of custody for these specific samples. It would be helpful if you could identify how many seeds of each variety you require, and identify the name and address of the appropriate recipient for delivery/shipping purposes.

As you probably know, the (b) (4) was ubiquitous both in the commercial market and in wheat breeding and varietal testing programs for many years. Indeed, (b) (4)

(b) (4), (b) (6), (b) (7)(C)

(b) (6), (b) (6)



Key Points Regarding USDA's Inquiry

At this stage in the inquiry, we believe it may be helpful to take a broader look at what information has emerged to date. We have three brief points to stress.

First, as you know, it has been conclusively established that the RR wheat detection in Oregon was an isolated event on a single field—as extensive testing by USDA, Washington State University, Monsanto and many other entities has demonstrated. This fact was very important to establish at the outset of USDA's inquiry last Spring, and no subsequent detections have been identified in any context over the past 10 months. Given that no RR wheat was found in the many hundreds of tests on commercial wheat, and that no RR wheat has been found on any other Oregon fields, we think it would be impossible for any objective fact-finder to conclude that serious flaws existed in Monsanto's RR wheat field trial program and protocols.

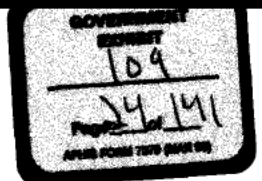
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(b) (4)

We thank you once again for your professional conduct of this inquiry and look forward to further discussions.

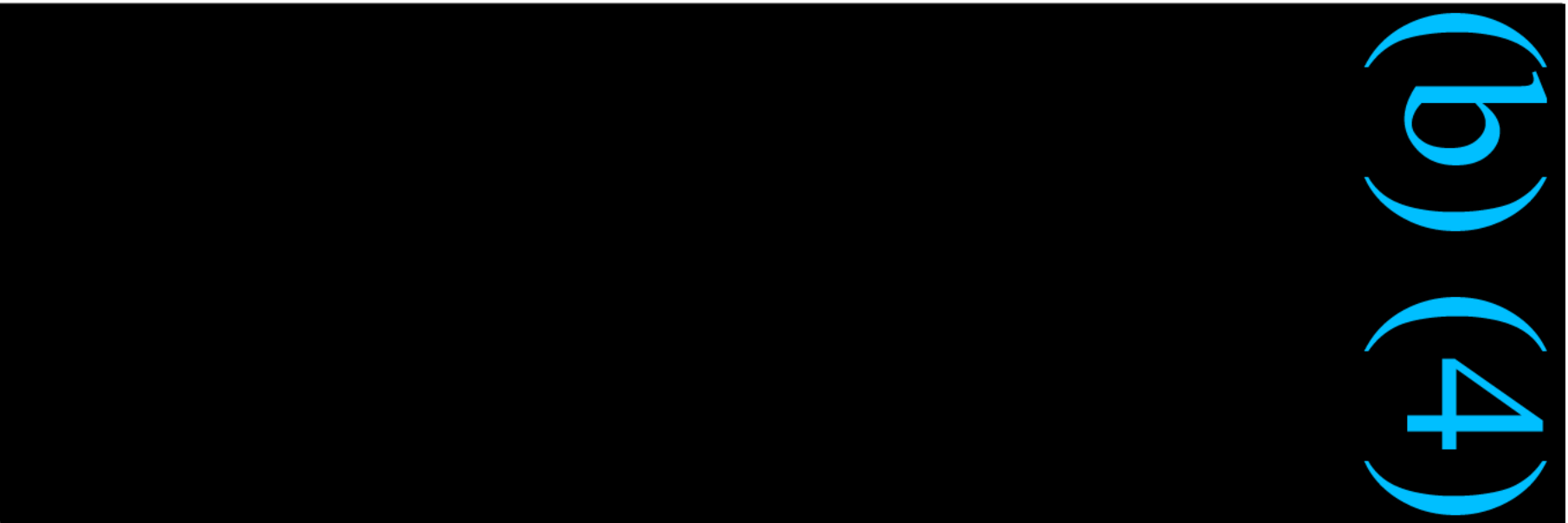
Sincerely,

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(b) (4)



(b) (4)

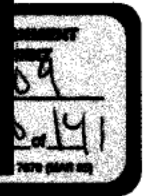
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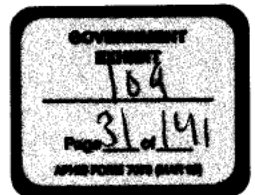
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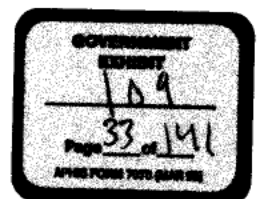
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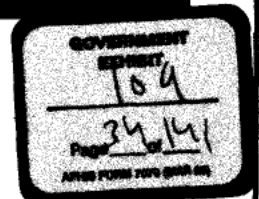
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(b) (4)

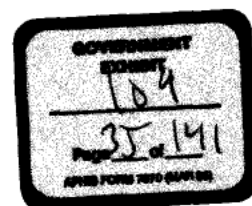


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(b) (4)



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May 1, 2011

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May 1, 2011

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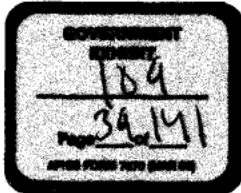
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March 21, 2011

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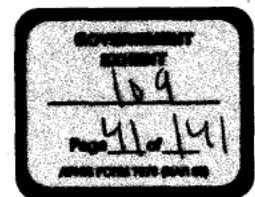
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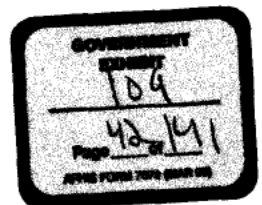
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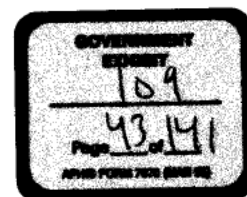


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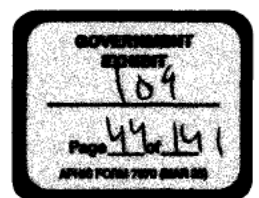
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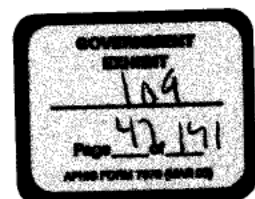
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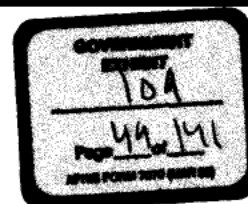
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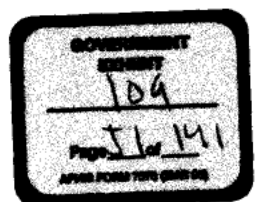
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(b) (4)

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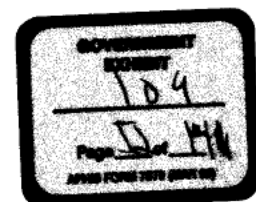
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RAPPORT



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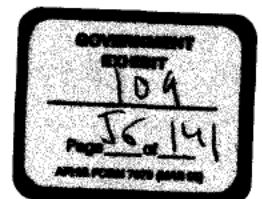
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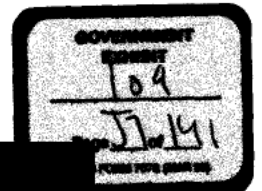
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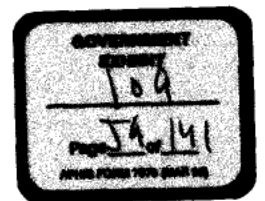
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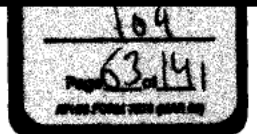
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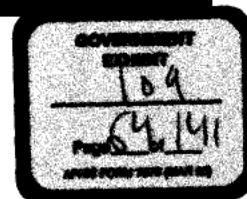
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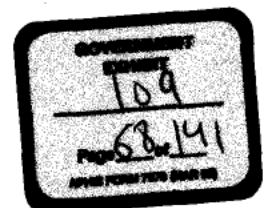
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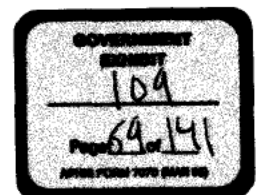
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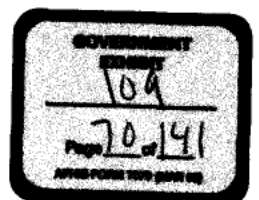
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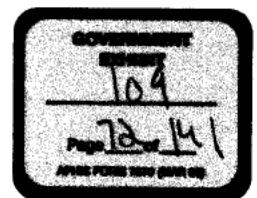
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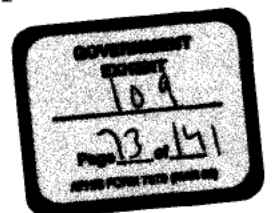
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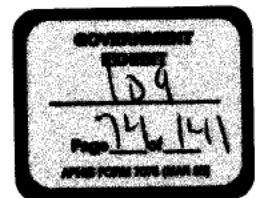
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Remaining seed from that provided for weed control plots was buried within the plot site at planting. All plots were destroyed prior to flower formation. Site is being monitored as per protocol.



(b) (4)

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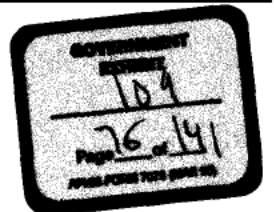
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Confidentiality Agreement

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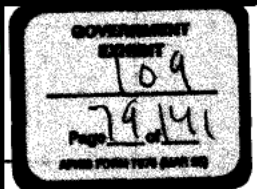


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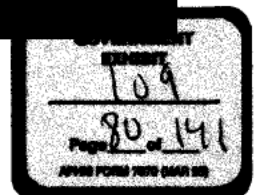
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700 CHESTERFIELD PARKWAY WEST
MAIL STOP GG3K
ST. LOUIS, MISSOURI 63017 USA

DATE February 28, 2005

TO

FROM

PHONE

SUBJECT

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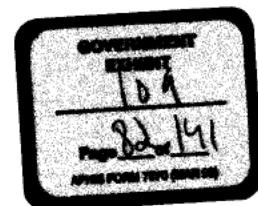
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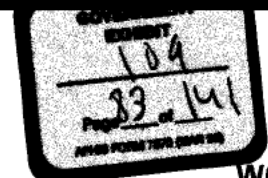
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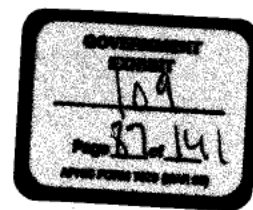
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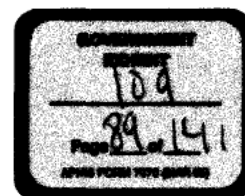


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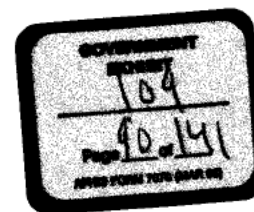


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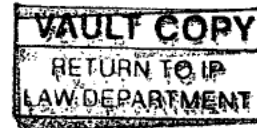
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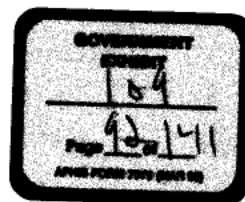
July 18, 2003

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(b) (4), (b) (6), (b) (7)(C)



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Compliance Packet

2000

Release (Field Trial) and Interstate Movement of Genetically Modified Plant Material

USDA Ref.# 00-195-04n

Monsanto Ref.# 2000-518XRAB

Crop: Wheat

Project Identifier: _____

Notification Requester:

_____ (b) (4), (b) (6), (b) (7)(C) _____

Phone No.: _____



OR120018_BR_003475

MONSANTO

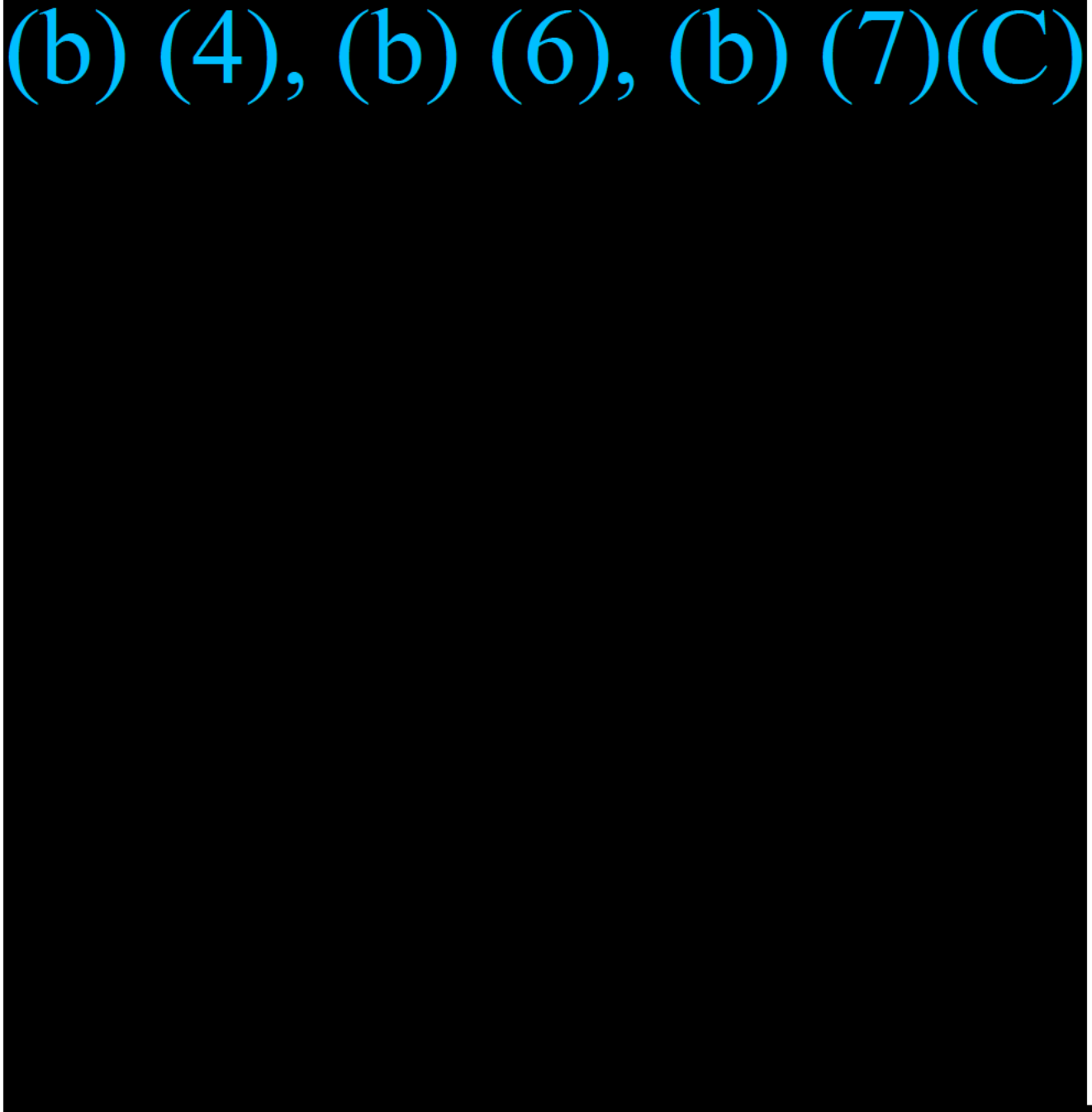
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September 1, 2000

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

(b) (4), (b) (6), (b) (7)(C)



AUTHORIZED FOR MOVEMENT ONLY

OR120018_BR_003477

CONFIDENTIAL BUSINESS INFORMATION

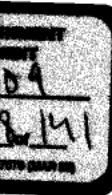
W0020090

(b) (4), (b) (6), (b) (7)(C)



OR120018_BR_003479

(b) (4)



(b) (4)

RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

(b) (4), (b) (6), (b) (7)(C)

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Fax (636) 737-7085

2

CONFIDENTIAL BUSINESS INFORMATION

W0020093

(b) (4)



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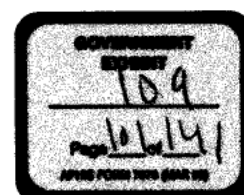
Fax (636) 737-7085

3

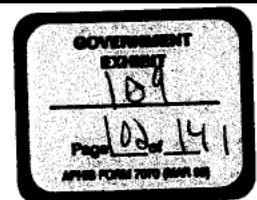
Monsanto Company - 700 Chesterfield Parkway North/BB3D- St. Louis, MO 63198

CONFIDENTIAL BUSINESS INFORMATION

W0020094



(b) (4)



RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

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Fax (636) 737-7085

CONFIDENTIAL BUSINESS INFORMATION

W0020096

(b) (4)



RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

(b) (4), (b) (6), (b) (7)(C)

Monsanto Company - 700 Chesterfield Parkway North/BR20 - St. Louis, MO 63198

Fax (636) 737-7085

CONFIDENTIAL BUSINESS INFORMATION

W0020097



Approvals



OR120018_BR_003493



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

August 31, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release

Notification no. 00-195-04n (2000-518XRAB)

Regulated article - Wheat

Destinations - Arizona, Hawaii, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

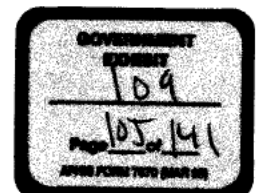
In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. (b) (6), (b) (7)(C) Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.



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OR120018_BR_003495

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W0020099

- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. (b) (6), (b) (7)(C) within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. (b) (6), (b) (7)(C) Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

(b) (6), (b) (7)(C) Arizona Dept. of Arizona, Phoenix, AZ
(b) (6), (b) (7)(C) Hawaii Dept. of Agric., Honolulu, HI
(b) (6), (b) (7)(C) Missouri Dept. of Agric., Jefferson City, MO
Montana Dept. of Agric., Helena, MT
PPQ, WR, Sacramento, CA
PPQ, SCR, Jefferson City, MO



OR120018_BR_003497

Notification Compliance Form

Monsanto Id: 2000-518XRAB **Date Requested:** 07/11/2000

USDA#: 00-195-04n **Date Submitted:** 07/12/2000

Requested By: (b) (6), (b) (7)(C) **Date Effective:** 08/31/2000

Compliance Specialist: (b) (6), (b) (7)(C)

Crop: Wheat **Subject:** Interstate Movement and Release

Trait: HT

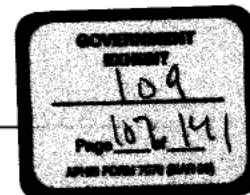
Monsanto Id Comment: WPB-2000-winter

Descriptor:

Special Instructions:

Admin. Assistant:

Date Compliance Packet Sent:



1. **Packet Type:** Movement **Canceled:** No

Site	Address	City	County/Province	State/Prov. Abbr.	Postal Code	Country
(b) (4)	(b) (4)	St. Louis		MO	(b) (4)	U.S.A.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID
2000-518XRAB

July 12, 2000

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

1. **USDA Reference Number**
2. **Applicant Reference Number** 2000-518XRAB
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

4. **Duration of Introduction**

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. **Recipient**

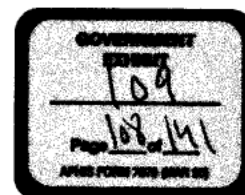
Wheat, Triticum aestivum

6. **Regulated Article**

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of BZ991-408HW, BZ992-588, Express, Impervo, Brooks, West Bred 926, West Bred 936, elite lines and Bobwhite



OR120018_BR_003501

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

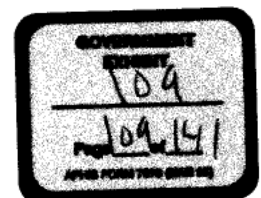
GENE OF INTEREST

Promoter: CMP3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



CBI-DELETED

Monsanto Reference ID

2000-518XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI



CBI-DELETED

Monsanto Reference ID
2000-518XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 8,000 kg. wheat seeds, seedlings and leaf tissue to and from each location.

ORIGIN:
AZ, HI, MO, MT

DESTINATION:
AZ, HI, MO, MT

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.



CBI-DELETED

Monsanto Reference ID
2000-518XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.



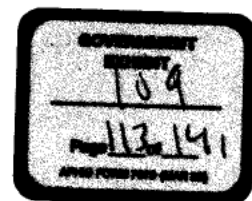
CBI-DELETED

Monsanto Reference ID

2000-518XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA



CBI-DELETED

Monsanto Reference ID
2000-518XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1), HI (1)

AZ

[CBI Deleted] -- Yuma County/Province, AZ, USA, 10 acres

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 4 acres



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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-518XRAB

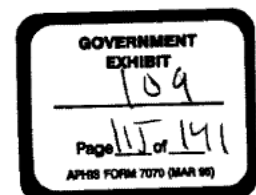
9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

July 12, 2000



OR120018_BR_003515

Contact	Company	Address	City	State/Prov. Abbr.	Postal Code	Country	Phone
(b) (4), (b) (6), (b) (7)(C)	(b) (4)	(b) (4)		MO	(b) (4)	U.S.A.	(b) (4), (b) (6), (b) (7)(C)

2. Packet Type: Movement Canceled: No

Site	Address	City	County/Province	State/Prov. Abbr.	Postal Code	Country
(b) (4)	(b) (4)		Gallatin	MT	(b) (4)	USA

Contact	Company	Address	City	State/Prov. Abbr.	Postal Code	Country	Phone
(b) (4), (b) (6), (b) (7)(C)	(b) (4)	(b) (4)		MT	(b) (4)	USA	(b) (4), (b) (6), (b) (7)(C)

3. Packet Type: Movement/Release Canceled: No

Site	Address	City	County/Province	State/Prov. Abbr.	Postal Code	Country
(b) (4)	(b) (4)		Honolulu	HI	(b) (4)	U.S.A.

Contact	Company	Address	City	State/Prov. Abbr.	Postal Code	Country	Phone
(b) (4), (b) (6), (b) (7)(C)	(b) (4)	(b) (4)		HI	(b) (4)	U.S.A.	(b) (4), (b) (6), (b) (7)(C)

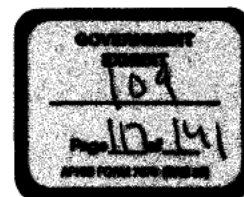
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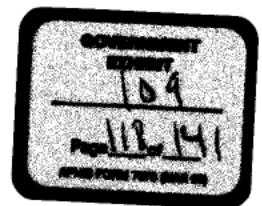


OR120018_BR_003516

Site	Address	City	County/Province	State/Prov. Abbr.	Postal Code	Country
(b) (4)	(b) (4)	Yuma		AZ	(b) (4)	USA

Contact	Company	Address	City	State/Prov. Abbr.	Postal Code	Country	Phone
(b) (4), (b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)	(b) (4), (b) (6), (b) (7)(C)		AZ	(b) (4), (b) (6), (b) (7)(C)	USA	(b) (4), (b) (6), (b) (7)(C)





WHEAT FIELD RELEASE

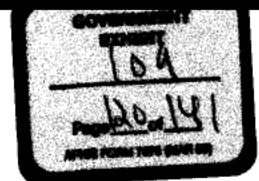
PERFORMANCE STANDARDS

(b)(4)



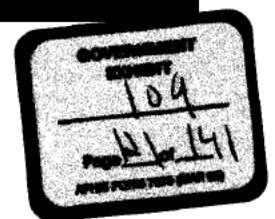
Wheat Performance Standards (Cont'd)

(b)(4)



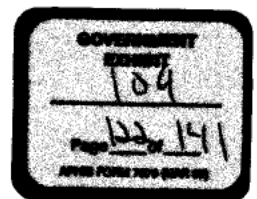
Wheat Performance Standards (Cont'd)

(b)(4)



Wheat Performance Standards (Cont'd)

(b)(4)





Compliance Forms



(b)(4)

(b)(4)

RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

(b) (6), (b) (7)(C)

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Fax (636) 737-7085

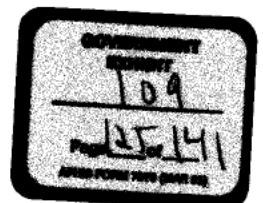


CONFIDENTIAL BUSINESS INFORMATION

W0020118

OR120018_BR_003532

(b)(4)



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OR120018_BR_003534

W0020119

(b)(4)



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W0020120

(b)(4)



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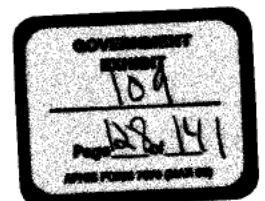
Fax (636) 737-7085

CONFIDENTIAL BUSINESS INFORMATION

OR120018_BR_003538

W0020121

(b)(4)



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Fax (636) 737-7086

Monsanto Company - 700 Chesterfield Parkway North/6330 - St. Louis, MO 63198

CONFIDENTIAL BUSINESS INFORMATION

W0020122

(b)(4)

(b)(4)



RETURN THIS COMPLETED FORM TO YOUR COMPLIANCE SPECIALIST:

(b) (6), (b) (7)(C)

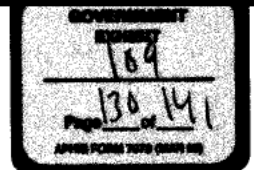
Fax (636) 737-7085

Monsanto Company - 700 Chesterfield Parkway North, BR3D - St. Louis, MO 63198

CONFIDENTIAL BUSINESS INFORMATION

W0020123

(b)(4)



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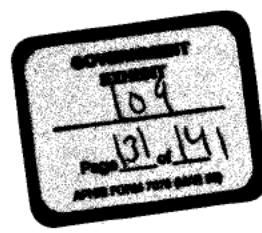
(b) (6), (b) (7)(C)

Monsanto Company - 700 Chesterfield Parkway North/BB3D - St. Louis, MO 63198

Fax (636) 737-7085

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W0020124

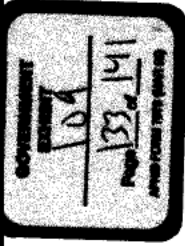


Other Information

(b)(4)

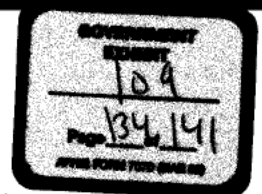


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(b)(4)

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- 1 -

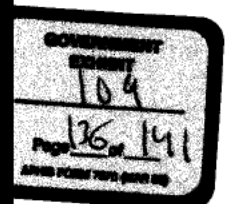
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(b)(4)

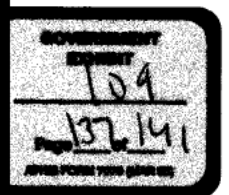


- 2 -

(b)(4)



(b)(4)



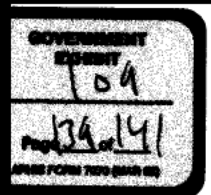
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(b)(4)



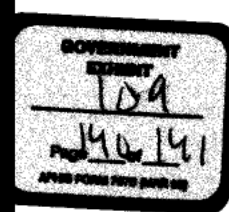
(b)(4)

(b)(4)



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(b)(4)



(b)(4)

(b)(4)



No.

9000012

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

Western Plant Breeders, Inc.

Whereas, THERE HAS BEEN PRESENTED TO THE

Secretary of Agriculture

AN APPLICATION REQUESTING A CERTIFICATE OF PROTECTION FOR AN ALLEGED NOVEL VARIETY OF SEXUALLY REPRODUCED PLANT, THE NAME AND DESCRIPTION OF WHICH ARE CONTAINED IN THE APPLICATION AND EXHIBITS, A COPY OF WHICH IS HEREUNTO ANNEXED AND MADE A PART HEREOF, AND THE VARIOUS REQUIREMENTS OF LAW IN SUCH CASES MADE AND PROVIDED HAVE BEEN COMPLIED WITH, AND THE TITLE THERETO IS, FROM THE RECORDS OF THE PLANT VARIETY PROTECTION OFFICE, IN THE APPLICANT(S) INDICATED IN THE SAID COPY, AND WHEREAS, UPON DUE EXAMINATION MADE, THE SAID APPLICANT(S) IS (ARE) ADJUDGED TO BE ENTITLED TO A CERTIFICATE OF PLANT VARIETY PROTECTION UNDER THE LAW.

NOW, THEREFORE, THIS CERTIFICATE OF PLANT VARIETY PROTECTION IS TO GRANT UNTO THE SAID APPLICANT(S) AND THE SUCCESSORS, HEIRS OR ASSIGNS OF THE SAID APPLICANT(S) FOR THE TERM OF *eighteen* YEARS FROM THE DATE OF THIS GRANT, SUBJECT TO THE PAYMENT OF THE REQUIRED FEES AND PERIODIC REPLENISHMENT OF VIABLE BASIC SEED OF THE VARIETY IN A PUBLIC REPOSITORY AS PROVIDED BY LAW, THE RIGHT TO EXCLUDE OTHERS FROM SELLING THE VARIETY, OR OFFERING IT FOR SALE, OR REPRODUCING IT, IMPORTING IT, OR EXPORTING IT, OR USING IT IN PRODUCING A HYBRID OR DIFFERENT VARIETY THEREFROM, TO THE EXTENT PROVIDED BY THE PLANT VARIETY PROTECTION ACT. UNITED STATES SEED OF THIS VARIETY (1) SHALL BE SOLD BY VARIETY NAME ONLY AS CERTIFIED SEED AND (2) SHALL CONFORM TO THE NUMBER OF GENERATIONS OF THE OWNER OF THE RIGHTS. (84 STAT. 1542, AS AMENDED, 7 U.S.C. 2321 ET SEQ.)

WHEAT

'Express'

In Testimony Whereof, I have hereunto set my hand and caused the seal of the Plant Variety Protection Office to be affixed at the City of Washington, D.C. this 28th day of May in the year of our Lord one thousand nine hundred and ninety-three.

Attest:

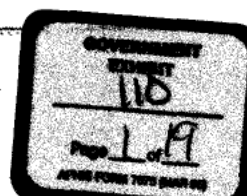
Kenneth Hoane

Commissioner

Plant Variety Protection Office
Agricultural Marketing Service

Mike Long
Secretary of Agriculture

OR120018_BR_003568



U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

APPLICATION FOR PLANT VARIETY PROTECTION CERTIFICATE

(Instructions on reverse)

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). Information is held confidential until certificate is issued (7 U.S.C. 2426).

1. NAME OF APPLICANT(S) (as it is to appear on the Certificate) Western Plant Breeders		2. TEMPORARY DESIGNATION OR EXPERIMENTAL NO. DA984-Q34	3. VARIETY NAME EXPRESS
4. ADDRESS (street and no. or R.F.D. no., city, state, and ZIP) 8111 Timberline Drive Bozeman, MT 59715 6720 W. Chicago St. #4 Chandler, AZ 85226		5. PHONE (include area code) (b) (6), (b) (7)(C), (b) (4)	FOR OFFICIAL USE ONLY PVPO NUMBER 9000012 Filing and Examination Fee: \$250.00 Date Oct. 16, 1989 Certificate Fee: \$250 Date Apr. 23, 1993
6. GENUS AND SPECIES NAME Triticum aestivum	7. FAMILY NAME (Botanical) Gramineae		
8. CROP KIND NAME (Common Name) Common Wheat	9. DATE OF DETERMINATION May 2, 1988		
10. IF THE APPLICANT NAMED IS NOT A "PERSON," GIVE FORM OF ORGANIZATION (Corporation, partnership, association, etc.) Corporation			
11. IF INCORPORATED, GIVE STATE OF INCORPORATION Maryland	12. DATE OF INCORPORATION Sept. 27, 1985		
13. NAME AND ADDRESS OF APPLICANT REPRESENTATIVE(S), IF ANY, TO SERVE IN THIS APPLICATION AND RECEIVE ALL PAPERS (b) (6), (b) (7)(C), (b) (4) Western Plant Breeders, 227 South Smith Rd., Suite #104 Tempe, AZ 85281 PHONE (include area code): (b) (6), (b) (7)(C), (b) (4)			

14. CHECK APPROPRIATE BOX FOR EACH ATTACHMENT SUBMITTED (Follow INSTRUCTIONS on reverse)

- a. ☒ Exhibit A, Origin and Breeding History of the Variety.
b. ☒ Exhibit B, Novelty Statement.
c. ☒ Exhibit C, Objective Description of Variety.
d. ☐ Exhibit D, Additional Description of Variety.
e. ☒ Exhibit E, Statement of the Basis of Applicant's Ownership.
f. ☒ Seed Sample (2,500 viable untreated seeds). Date Seed Sample mailed to Plant Variety Protection Office Oct. 6 1989.
g. ☒ Filing and Examination Fee (\$2,150) made payable to "Treasurer of the United States."

15. DOES THE APPLICANT(S) SPECIFY THAT SEED OF THIS VARIETY BE SOLD BY VARIETY NAME ONLY AS A CLASS OF CERTIFIED SEED? (See section 83(a) of the Plant Variety Protection Act.)

☒ YES (If "YES," answer items 16 and 17 below)

☐ NO (If "NO," skip to item 18 below)

16. DOES THE APPLICANT(S) SPECIFY THAT THIS VARIETY BE LIMITED AS TO NUMBER OF GENERATIONS?

☐ YES

☒ NO

17. IF "YES" TO ITEM 16, WHICH CLASSES OF PRODUCTION BEYOND BREEDER SEED?

☐ FOUNDATION

☐ REGISTERED

☐ CERTIFIED

18. DID THE APPLICANT(S) PREVIOUSLY FILE FOR PROTECTION OF THE VARIETY IN THE U.S.?

☐ YES (If "YES," through ☐ Plant Variety Protection Act

☐ Patent Act. Give date: _____.)

☒ NO

19. HAS THE VARIETY BEEN RELEASED, USED, OFFERED FOR SALE, OR MARKETING IN THE U.S. OR OTHER COUNTRIES?

☐ YES (If "YES," give names of countries and dates)

☒ NO

20. The applicant(s) declare(s) that a viable sample of basic seeds of this variety will be furnished with the application and will be replenished upon request in accordance with such regulations as may be applicable.

The undersigned applicant(s) is (are) the owner(s) of this sexually reproduced novel plant variety, and believe(s) that the variety is distinct, uniform, and stable as required in section 41, and is entitled to protection under the provisions of section 42 of the Plant Variety Protection Act.

Applicant(s) is (are) informed that false representation herein can jeopardize protection and result in penalties.

SIGNATURE OF APPLICANT (Owner(s)) (b) (6), (b) (7)(C), (b) (4)	CAPACITY OR TITLE Wheat Breeder	DATE Oct. 6, 1989
SIGNATURE OF APPLICANT (Owner(s))	CAPACITY OR TITLE	DATE

OR120018_BR_003570

14.A 'EXPRESS'

25
8/14/80

DA984-034 is a spring wheat selected from the cross Veery/BH1146. From the F₂ grown at Klamath Falls, Oregon in 1982 selected heads were bulked and the resulting F₃ was grown at Yuma, Arizona in 1983. Six head selections made from this bulk were planted as F₄ rows at Dixon, California in 1984. One head was selected from each row and was grown as an F₅ head row at Woodland, California in 1985. One row was bulked and was designated 8630034. 8630034 was yield tested in Davis, California 1986. 8630034 was then designated DA984-034 and tested in both California and Arizona in 1987, 1988 and 1989. Thirty two heads were selected from the F₆ bulk at Phoenix in May of 1988 and grown as head rows in Bozeman, Montana in the summer of 1988. Five non-segregating rows that appeared to have identical phenotypes were harvested and were planted separately as row plots in Phoenix, Arizona in 1989. All five row plots were found to be non-segregating and were bulked together to produce pre-breeders seed. This seed was used to produce one acre of breeders seed in Bozeman, Montana the summer of 1989. A variant that is similar to DA984-034 but is 3 to 5 inches taller occurs at a frequency of two per pound. No other identifiable variants have been found during the multiplication process. DA984-034 is a stable and uniform cultivar in agronomic appearance and performance across several generations and growing conditions. Agronomic data to support stability is presented in the tables.

A white kernel variant occurs at a frequency of [?] .1 percent,
AAA 7 Nov 1995 letter



Western Plant Breeders

"Breeders of WestBred™ Varieties"

9000012

January 14, 1993

Mr. Alan A. Atchley
USDA/AMS/SD
Plant Variety Protection Office
10301 Baltimore Blvd.
Beltsville, MD 20705-2351

SUBJECT: PV Application No. 9000012, Wheat variety 'Express'

Dear Mr. Atchley:

The selection criteria that were used during the breeding of 'Express' were many and varied depending upon the stage of breeding. The selection criteria used up until the date of determination were high yield, high per cent protein, good test weight, good lodging resistance, semidwarf growth habit, acceptable flowering date, stripe rust resistance, leaf rust resistance, high yield under heavy Septoria tritici disease pressure and high sedimentation values.

'Express' can be distinguish from the variety 'Spillman' in that 'Express' is 5.7 inches shorter than 'Spillman'. (See table for t-Test) 'Express' is day length insensitive while 'Spillman' is day length sensitive. In 1992 at Phoenix Arizona, 'Express' headed on March 21, 1992 while Spillman headed on April 8, 1992. Grown at northern latitudes under long days, 'Express' and 'Spillman' have similar heading dates.

Enclosed please find one Exhibit C form for the variety 'Yolo' filled out by Western Plant Breeders. The breeder of 'Yolo' did not return a completed Exhibit C form even after several requests.

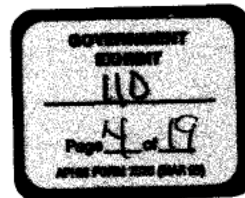
I believe this answers all of your questions and should allow the completion of the examination.

Sincerely:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Enclosures: Exhibit C form
t-Test table

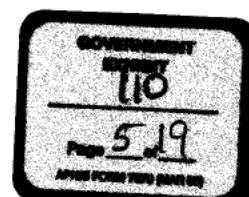


9000012

25
8/14/90
14.B 'EXPRESS'

DA984-034 is a day length insensitive, hard red spring wheat with an average height of 33.9 inches which is .4 inches taller than Yolo and 5.6 inches taller than Yecora Rojo. DA984-034 most resembles Yolo. DA984-034 differs from Yolo in that it has oblique glume shoulders while Yolo has elevated glume shoulders. DA984-034 has white colored chaff at maturity while Yolo has cream colored chaff at maturity. The head length of DA984-034 is significantly longer than the head length of Yolo. DA984-034 has significantly higher protein as well as much better baking characteristics than Yolo. The above comparisons along with the objective description (13C) show DA984-034 to be a novel variety of spring wheat.

OR120018_BR_003576



U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
LIVESTOCK, MEAT, GRAIN AND SEED DIVISION
BELTSVILLE, MARYLAND 20785
OBJECTIVE DESCRIPTION OF VARIETY
WHEAT (TRITICUM SPP.)

EXHIBIT C
(Wheat)

INSTRUCTIONS: See Reverse.

NAME OF APPLICANT(S)

Western Plant Breeders

ADDRESS (Street and No. or R.F.D. No., City, State, and ZIP Code)

8111 TIMBERLINE DRIVE
BOZEMAN, MT. 59715

FOR OFFICIAL USE ONLY

PVPO NUMBER

9000012

VARIETY NAME OR TEMPORARY
DESIGNATION

DA984-034 EXPRESS

Place the appropriate number that describes the varietal character of this variety in the boxes below.

Place a zero in first box (e.g. or) when number is either 99 or less or 9 or less.

1. KIND:

 1 = COMMON 2 = DURUM 3 = EMMER 4 = SPELT 5 = POLISH 6 = POULARD 7 = CLUB

2. TYPE:

 1 = SPRING 2 = WINTER 3 = OTHER (Specify) 1 = SOFT 2 = HARD 3 = OTHER (Specify) 1 = WHITE 2 = RED 3 = OTHER (Specify)

3. SEASON - NUMBER OF DAYS FROM EMERGENCE TO:

 FIRST FLOWERING LAST FLOWERING

4. MATURITY (50% Flowering):

 NO. OF DAYS EARLIER THAN 1 = ARTHUR 2 = SCOUT 3 = CHRIS
 NO. OF DAYS LATER THAN 4 = LEMHI 5 = NUGAINE 6 = LEEDS
7 = Yecora Rojo

5. PLANT HEIGHT (From soil level to top of head):

 CM. HIGH 7. = Yolo
 CM. TALLER THAN 1 = ARTHUR 2 = SCOUT 3 = CHRIS
 CM. SHORTER THAN 4 = LEMHI 5 = NUGAINE 6 = LEEDS

6. PLANT COLOR AT BOOTING (See reverse):

 1 = YELLOW GREEN 2 = GREEN 3 = BLUE GREEN

7. ANTHUR COLOR:

 1 = YELLOW 2 = PURPLE

8. STEM:

 Anthocyanin: 1 = ABSENT 2 = PRESENT Waxy Bloom: 1 = ABSENT 2 = PRESENT Hairiness of last internode of rachis: 1 = ABSENT 2 = PRESENT Internodes: 1 = HOLLOW 2 = SOLID NO. OF NODES (Originating from node above ground) CM. INTERNODE LENGTH BETWEEN FLAG LEAF AND LEAF BELOW

9. AURICLES:

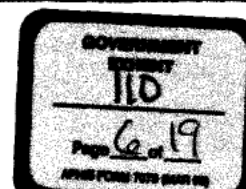
 Anthocyanin: 1 = ABSENT 2 = PRESENT Hairiness: 1 = ABSENT 2 = PRESENT

10. LEAF:

 Flag leaf at booting stage: 1 = ERECT 2 = RECURVED
3 = OTHER (Specify): Flag leaf: 1 = NOT TWISTED 2 = TWISTED Hairs of first leaf sheath: 1 = ABSENT 2 = PRESENT Waxy bloom of flag leaf sheath: 1 = ABSENT 2 = PRESENT MM. LEAF WIDTH (First leaf below flag leaf) CM. LEAF LENGTH (First leaf below flag leaf)

FORM LMGS 470-6 (6-82) (Formerly Form LPS 470-6 (3-79), which may be used)

OR120018_BR_003578



11. HEAD:

- ☐ 1 Density: 1 = LAX 2 = DENSE ☐ 2 Shape: 1 = TAPERING 2 = STRAP 3 = CLAVATE
4 = OTHER (Specify) _____
- ☐ 4 Awnedness: 1 = AWNLESS 2 = APICALLY AWNLETED 3 = AWNLETED 4 = AWNED
- ☐ 1 Color at maturity: 1 = WHITE 2 = YELLOW 3 = PINK 4 = RED
5 = BROWN 6 = BLACK 7 = OTHER (Specify): _____
- ☐ 1 0 CM. LENGTH ☐ 1 4 MM. WIDTH

12. GLUMES AT MATURITY:

- ☐ 3 Length: 1 = SHORT (CA. 7 mm.) 2 = MEDIUM (CA. 8 mm.) 3 = LONG (CA. 9 mm.) ☐ 3 Width: 1 = NARROW (CA. 3 mm.) 2 = MEDIUM (CA. 3.5 mm.)
3 = WIDE (CA. 4 mm.)
- ☐ 2 Shoulder: 1 = WANTING 2 = OBLIQUE 3 = ROUNDED
shape: 4 = SQUARE 5 = ELEVATED 6 = APICULATE ☐ 3 Beak: 1 = OBTUSE 2 = ACUTE 3 = ACUMINATE

13. COLEOPTILE COLOR:

- ☐ 1 1 = WHITE 2 = RED 3 = PURPLE

14. SEEDLING ANTHOCYANIN:

- ☐ 1 1 = ABSENT 2 = PRESENT

15. JUVENILE PLANT GROWTH HABIT:

- ☐ 3 1 = PROSTRATE 2 = SEMI-ERECT 3 = ERECT

16. SEED:

- ☐ 3 Shape: 1 = OVATE 2 = OVAL 3 = ELLIPTICAL ☐ 1 Cheek: 1 = ROUNDED 2 = ANGULAR
- ☐ 2 Brush: 1 = SHORT 2 = MEDIUM 3 = LONG ☐ 1 Brush: 1 = NOT COLLARED 2 = COLLARED
- ☐ Phenol reaction 1 = IVORY 2 = FAWN 3 = LT. BROWN
(See instructions): 4 = BROWN 5 = BLACK
- ☐ 3 Color: 1 = WHITE 2 = AMBER 3 = RED 4 = PURPLE 5 = OTHER (Specify) _____
- ☐ 0 7 MM. LENGTH ☐ 0 4 MM. WIDTH ☐ 4 5 GM. PER 1000 SEEDS

17. SEED CREASE:

- ☐ 1 Width: 1 = 60% OR LESS OF KERNEL 'WINOKA'
2 = 80% OR LESS OF KERNEL 'CHRIS'
3 = NEARLY AS WIDE AS KERNEL 'LEMHI'
- ☐ 2 Depth: 1 = 20% OR LESS OF KERNEL 'SCOUT'
2 = 35% OR LESS OF KERNEL 'CHRIS'
3 = 50% OR LESS OF KERNEL 'LEMHI'

18. DISEASE: (0 = Not Tested, 1 = Susceptible, 2 = Resistant)

- ☐ 0 STEM RUST (Races) ☐ 2 LEAF RUST Prevalent
(Races) races in CA. ☐ 2 STRIPE RUST Prevalent
(Races) races in CA. ☐ 0 LOOSE SMUT
- ☐ 2 POWDERY MILDEW ☐ 0 BUNT ☐ 2 OTHER (Specify) Septoria Tritici

19. INSECT: (0 = Not Tested, 1 = Susceptible, 2 = Resistant)

- ☐ 0 SAWFLY ☐ 0 APHID (Bydv.) ☐ 0 GREEN BUG ☐ 0 CEREAL LEAF BEETLE
- ☐ 0 OTHER (Specify) _____ HESSIAN FLY } ☐ 0 GP ☐ 0 A ☐ 0 B ☐ 0 C
RACES: ☐ 0 D ☐ 0 E ☐ 0 F ☐ 0 G

20. INDICATE WHICH VARIETY MOST CLOSELY RESEMBLES THAT SUBMITTED:

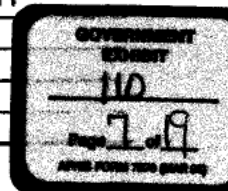
CHARACTER	NAME OF VARIETY	CHARACTER	NAME OF VARIETY
Plant tillering	Yo10	Seed size	Yo10
Leaf size	Yo10	Seed shape	Yo10
Leaf color	Yo10	Coleoptile elongation	Yo10
Leaf carriage	Yo10	Seedling pigmentation	Yo10

INSTRUCTIONS

GENERAL: The following publications may be used as a reference aid for the standardization of terms and procedures for completing this form:

- (a) L.W. Briggie and L. P. Reitz, 1963, Classification of Triticum Species and Wheat Varieties Grown in the United States, Technical Bulletin 1278, United States Department of Agriculture.
- (b) W.E. Walls, 1965, A Standardized Phenol Method for Testing Wheat Seeds for Varietal Purity, contribution No. 28 to the handbook of seed testing prepared by the Association of Official Seed Analysts. (See attachment.)

LEAF COLOR: Nickerson's or any recognized color fan should be used to determine the leaf color of the described variety.



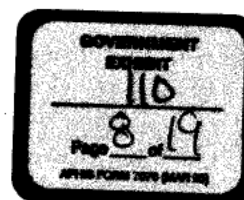
9000012

'EXPRESS'
Yield in lbs/acre of ~~DA984-034~~ and presently
grown cultivars in Western Plant Breeders trials

Σ
8/14/90

<u>Location</u>	<u>Year</u>	<u>DA984-034</u>	<u>Yecora Rojo</u>	<u>Yolo</u>	<u>Tadinia</u>
(b) (4)	CA 1986	5535	3265	4010	-
	1987	5708	5424	6369	6728
	1988	5684	6013	6496	5858
	1989	6738	7096	6945	6087
	AZ 1987	6350	5250	5850	6700
	1988	5112	5184	6336	5670
	1989	6067	4902	5632	4506
	CA 1987	6585	5869	5630	6346
	CA 1987	6670	5916	6235	5568
	1989	7031	6215	6664	5902
	CA 1987	5040	5640	4620	5160
	CA 1988	6764	5349	6256	5222
(b) (4)	CA 1988	6432	5904	6696	6312
	1989	5358	5032	6229	5236
Average		6077	5504	5998	

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7

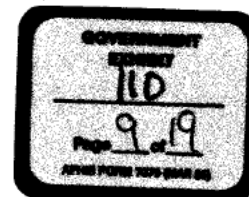
9000012

'EXPRESS'

Percent Protein of ~~DA984-034~~ and presently grown
cultivars in Western Plant Breeders trials.

'EXPRESS'

Location	Year	DA984-034	Yecora Rojo	Yolo	Tadinia
(b) (4) CA	1986	14.2	14.3	12.6	-
	1987	14.3	12.6	12.1	11.8
	1988	13.0	12.2	10.5	11.5
(b) (4) AZ	1987	14.7	14.7	13.6	13.9
	1988	12.3	10.7	9.4	9.6
(b) (4) CA	1987	14.8	15.0	13.8	14.3
(b) (4) CA	1988	15.6	14.8	13.3	12.7
(b) (4) CA	1988	11.3	11.4	10.6	11.0
Average		13.8	13.2	12.0	

25
8/14/90

9000012

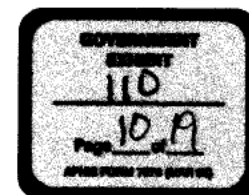
'EXPRESS'

Test Weight in lbs/bu of ~~DA984-034~~ and presently
grown varieties in Western Plant Breeders trials.

'EXPRESS'

<u>Location</u>	<u>Year</u>	<u>DA984-034</u>	<u>Yecora Rojo</u>	<u>Yolo</u>	<u>Tadinia</u>
(b) (4) CA	1986	63.6	61.4	61.7	-
	1987	65.4	66.4	66.5	64.6
	1988	65.8	66.0	65.8	64.5
(b) (4) AZ	1987	62.1	62.4	61.6	61.0
	1988	65.6	66.2	65.2	65.4
(b) (4) CA	1987	63.8	61.1	62.4	60.9
(b) (4) CA	1988	63.7	64.7	63.0	63.0
Average		64.3	64.0	63.7	

Σ
8/4/90



9000012

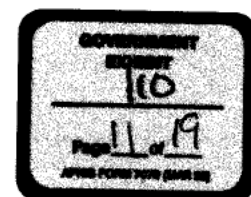
'EXPRESS'

Plant Height in inches of ~~DA984-034~~ and presently
grown cultivars in Western Plant Breeders trials.

'EXPRESS'

<u>Location</u>	<u>Year</u>	<u>DA984-034</u>	<u>Yecora Rojo</u>	<u>Yolo</u>	<u>Tadinia</u>
(b) (4) CA	1986	35	28	36	-
	1988	38	31	36	38
(b) (4) AZ	1988	36	30	37	36
	1989	34	27	31	33
(b) (4) CA	1988	30	23	30	29
(b) (4) CA	1988	30	28	32	36
	1989	33	27	31	35
(b) (4) CA	1989	35	32	35	37
Average		33.9	28.3	33.5	

2/14/90



9000012

'EXPRESS'

Date of flowering of ~~DA984-034~~ and presently
grown cultivars in Western Plant Breeders trials.

'EXPRESS'

<u>Location</u>	<u>Year</u>	<u>DA984-034</u>	<u>Yecora Rojo</u>	<u>Yolo</u>	<u>Tadinia</u>
(b) (4) CA	1986	3-25	3-18	3-30	-
(b) (4) AZ	1987	3-20	3-12	3-18	3-16
	1988	3-27	3-20	3-26	3-23
	1989	3-18	3-10	3-16	3-17

25
8/14/80

OR120018_BR_003590



11

'EXPRESS'

Rust resistant ratings of ~~DA984-034~~ and presently grown cultivars in Western Plant Breeders trials.*

Leaf Rust

'EXPRESS'

Location Year ~~DA984-034~~ Yecora Rojo Yolo Tadinia

(b) (4)

Location	Year	DA984-034	Yecora Rojo	Yolo	Tadinia
(b) (4)	1988	1	4	3	4
	1989	1	-	5	5

susceptible
check
WRP 9-5

Stripe Rust

Location	Year	DA984-034	Yecora Rojo	Yolo	Tadinia	susceptible check WRP 9-5
(b) (4)	1988	0	0	0	0	6
	1989	0	1	0	0	9

* 0=none, 9=dead



9000012

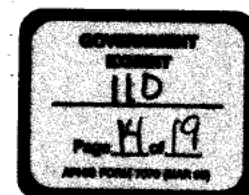
Septoria tritici disease rating of ~~DA984-034~~ and
presently grown cultivars in Western Plant Breeders trials*

'EXPRESS'

<u>Location</u>	<u>Year</u>	<u>DA984-034</u>	<u>Yecora Rojo</u>	<u>Yolo</u>	<u>Tadinia</u>
(b) (4) CA	1986	2.0	5.7	2.3	-
	1989	1.0	4.0	2.0	1.0

* 0=none, 9=dead

8/14/80



'EXPRESS'
Sedimentation values of ~~DA984-034~~ and presently grown
cultivars in Western Plant Breeders trials.

'EXPRESS'
~~DA984-034~~ Yecora Rojo Yolo Tadinia

Location	Year	DA984-034	Yecora Rojo	Yolo	Tadinia
(b) (4) CA	1986	46	57	38	
	1987	83	69	67	57
	1988	68	74	51	46
(b) (4) AZ	1988	63	57	45	42
(b) (4) CA	1987	68	76	60	58
(b) (4) CA	1988	67	75	57	62
(b) (4) CA	1988	69	62	57	54
Average		<u>66</u>	<u>67</u>	<u>54</u>	

8/17/80

t-Test comparison of average percent
protein of ~~DA984-034~~ and Yolo

~~EXPRESS~~ ~~EXPRESS~~
 \bar{x} ~~DA984-034~~ = 14.0

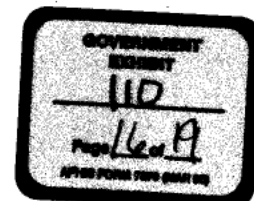
\bar{x} Yolo = 11.7

t with 30 df = $2.3/.5318 = 4.32^{***}$

*** Significant at .001 level

~~EXPRESS~~

DA984-034	Yolo
14.2	12.6
14.3	12.1
13.0	10.5
14.7	13.6
12.3	9.4
14.8	13.8
15.6	13.3
11.3	10.6
15.4	11.5
11.4	10.2
13.4	11.7
14.3	8.4
14.1	13.4
15.0	13.7
15.4	10.7
14.2	12.1
14.0	11.7



9000012

t-Test comparison of average head length
of ~~DA984-034~~ and Yolo.

- 'EXPRESS' 'EXPRESS'
x ~~DA984-034~~ = 10.3

- x Yolo = 7.8

t with 18 df = $2.5 / .2458 = 10.17^{***}$

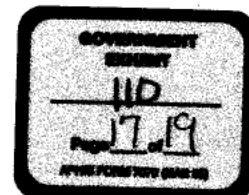
*** Significant at .001 level

'EXPRESS'

~~DA984-034~~

Yolo

11.1	cm	8.5
10.6		8.2
9.9		7.3
10.3		8.0
9.1		7.5
9.9		7.6
11.2		8.0
10.5		7.2
10.8		7.5
9.7		7.8



'EXPRESS'
 Quality Evaluation of ~~DA984-034~~, Yolo, Baker, and
 Yecora Rojo in the California Extension Trials. *

	Flour				Mixograph		Baking			
	yld	ash	mscr	pro	absr	ty	absr	mxt	lvol	bcr
Butte 1988										
'EXPRESS'										
DA984-034	70.8	.35	87.9	12.2	64.6	2H	66.3	2.2	931	5
Yolo	72.4	.36	89.0	9.7	60.1	3M	60.3	2.3	811	8
Baker	69.1	.36	85.7	9.7	63.2	4M	65.9	3.3	926	8
YecoraRojo	73.4	.36	90.1	10.3	63.2	4M	64.4	2.8	863	3
U.C. Davis 1988										
'EXPRESS'										
DA984-034	68.5	.36	85.4	12.1	62.7	6M	64.9	1.8	847	6
Yolo	72.7	.34	90.7	9.3	60.5	2M	61.2	1.9	810	9
Baker	71.2	.41	85.4	11.5	64.0	5H	65.7	3.1	869	2
YecoraRojo	72.5	.46	84.1	11.2	64.6	5H	64.3	3.3	838	4
Sacramento - San Joaquin Delta										
'EXPRESS'										
DA984-034	73.1	.33	91.6	13.3	64.7	2H	64.9	2.1	897	3
Yolo	74.4	.36	91.3	9.8	61.1	2H	60.8	1.7	889	9
Baker	72.9	.33	91.0	10.4	62.7	2M	61.9	1.3	847	8
YecoraRojo	74.3	.34	92.3	12.1	64.4	5H	66.1	4.0	887	2

* Quality analyses were performed by the:
 Western Wheat Quality Laboratory, USDA,
 Pullman, WA

yld= flour extraction percentage
 ash= flour ash percentage
 mscr=milling score
 pro= flour protein, 14% m.b.
 absr=absorption at 14% m.b. corrected to 11% protein
 ty= mixograph type
 mxt= mix time- optimum
 lvol=loaf volume (c.c.) corrected to 11% protein
 bcr= bread crumb rating, 1=excellent, 5=fair, 9=poor



9000012

14.E

Western Plant Breeders, Inc. is the employer of the breeder, [REDACTED] and rightfully, therefore, the owner of ~~DA984-034~~.

'EXPRESS'

ES
8/14/80

OR120018_BR_003604



18

No.

200800002

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

West Bred, LLC

Whereas, THERE HAS BEEN PRESENTED TO THE

Secretary of Agriculture

AN APPLICATION REQUESTING A CERTIFICATE OF PROTECTION FOR AN ALLEGED DISTINCT VARIETY OF SEXUALLY REPRODUCED, OR TUBER PROPAGATED PLANT, THE NAME AND DESCRIPTION OF WHICH ARE CONTAINED IN THE APPLICATION AND EXHIBITS, A COPY OF WHICH IS HEREUNTO ANNEXED AND MADE A PART OF THIS CERTIFICATE, AND THE VARIOUS REQUIREMENTS OF LAW IN SUCH CASES MADE AND PROVIDED HAVE BEEN COMPLIED WITH, AND THE TITLE THEREOF IS FROM THE RECORDS OF THE PLANT VARIETY PROTECTION OFFICE, IN THE APPLICANT(S) INDICATED IN THE SAID COPY, AND WHEREAS, UPON DUE CONSIDERATION MADE, THE SAID APPLICANT(S) IS (ARE) ADJUDGED TO BE ENTITLED TO A CERTIFICATE OF PLANT VARIETY PROTECTION UNDER THE LAW.

WHEREFORE, THIS CERTIFICATE OF PLANT VARIETY PROTECTION IS TO GRANT UNTO THE SAID APPLICANT(S) AND THE SUCCESSORS, HEIRS OR ASSIGNS OF THE SAID APPLICANT(S) FOR THE TERM OF TWENTY YEARS FROM THE DATE OF THIS GRANT, SUBJECT TO THE PAYMENT OF THE REQUIRED FEES AND PERIODIC DEPOSITS OF VIABLE BASIC SEED OF THE VARIETY IN A PUBLIC REPOSITORY AS PROVIDED BY LAW, THE APPLICANT(S) AND OTHERS FROM SELLING THE VARIETY, OR OFFERING IT FOR SALE, OR REPRODUCING IT, OR IMPORTING IT, OR CONDITIONING IT FOR PROPAGATION, OR STOCKING IT FOR ANY OF THE FOREGOING, OR USING IT IN PRODUCING A HYBRID OR DIFFERENT VARIETY THEREFROM, TO THE EXTENT PROVIDED IN THE PLANT VARIETY PROTECTION ACT. (84 STAT. 1542, AS AMENDED, 7 U.S.C. 2321 ET SEQ.)

WHEAT, COMMON

'Expresso'

In Testimony Whereof, I have hereunto set my hand and caused the seal of the Plant Variety Protection Office to be affixed at the City of Washington, D.C. this seventh day of December, in the year two thousand and seven.

Attest:

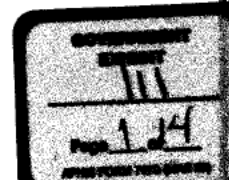
Blm Zue

Commissioner
Plant Variety Protection Office
Agricultural Marketing Service

Edmund T. Schaefer

Secretary of Agriculture

OR120018 BR 003606



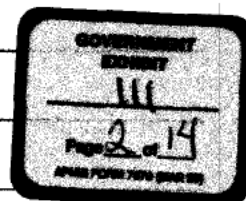
U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY - PLANT VARIETY PROTECTION OFFICE

APPLICATION FOR PLANT VARIETY PROTECTION CERTIFICATE
(Instructions and information collection burden statement on reverse)

The following statements are made in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the Paperwork Reduction Act (PRA) of 1995.

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). Information is held confidential until certificate is issued (7 U.S.C. 2426).

1. NAME OF OWNER WestBred, LLC		2. TEMPORARY DESIGNATION OR EXPERIMENTAL NAME DA984-034SRR		3. VARIETY NAME Expresso	
4. ADDRESS (Street and No., or R.F.D. No., City, State, and ZIP Code, and Country) 81 Timberline Drive Bozeman, MT 59718		5. TELEPHONE (include area code) (b) (6), (b) (7)(C)		FOR OFFICIAL USE ONLY PVPO NUMBER #200800002 FILING DATE OCTOBER 10, 2007	
		6. FAX (include area code) 406-586-8247			
7. IF THE OWNER NAMED IS NOT A "PERSON", GIVE FORM OF ORGANIZATION (corporation, partnership, association, etc.) WestBred, LLC		8. IF INCORPORATED, GIVE STATE OF INCORPORATION Arizona		9. DATE OF INCORPORATION August 4, 2003	
10. NAME AND ADDRESS OF OWNER REPRESENTATIVE(S) TO SERVE IN THIS APPLICATION. (First person listed will receive all papers) (b) (6), (b) (7)(C) WestBred, LLC P.O. Box 6904 Yuma, AZ 85366				FILING AND EXAMINATION FEES: \$ 4,382.00 DATE 10/10/07 CERTIFICATION FEE: \$ 768.00 DATE 10/23/2007	
11. TELEPHONE (include area code) (b) (6), (b) (7)(C)		12. FAX (include area code) 928-782-2751		13. E-MAIL (b) (6), (b) (7)(C)@westbred.com	
14. CROP KIND (Common Name) Common Wheat		16. FAMILY NAME (Botanical) Poaceae		15. DOES THE VARIETY CONTAIN ANY TRANSGENES? (OPTIONAL) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF SO, PLEASE GIVE THE ASSIGNED USDA-APHIS REFERENCE NUMBER FOR THE APPROVED PETITION TO DEREGULATE THE GENETICALLY MODIFIED PLANT FOR COMMERCIALIZATION.	
15. GENUS AND SPECIES NAME OF CROP Triticum aestivum		17. IS THE VARIETY A FIRST GENERATION HYBRID? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		20. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE SOLD ONLY AS A CLASS OF CERTIFIED SEED? (See Section 83(a) of the Plant Variety Protection Act) <input type="checkbox"/> YES (If "yes", answer items 21 and 22 below) <input checked="" type="checkbox"/> NO (If "no", go to item 23) <input type="checkbox"/> UNDECIDED	
19. CHECK APPROPRIATE BOX FOR EACH ATTACHMENT SUBMITTED (Follow instructions on reverse) a. <input checked="" type="checkbox"/> Exhibit A. Origin and Breeding History of the Variety b. <input checked="" type="checkbox"/> Exhibit B. Statement of Distinctness c. <input checked="" type="checkbox"/> Exhibit C. Objective Description of Variety d. <input type="checkbox"/> Exhibit D. Additional Description of the Variety (Optional) e. <input checked="" type="checkbox"/> Exhibit E. Statement of the Basis of the Owner's Ownership f. <input checked="" type="checkbox"/> Exhibit F. Declaration Regarding Deposit g. <input checked="" type="checkbox"/> Voucher Sample (3,000 viable untreated seeds or, for tuber propagated varieties, verification that tissue culture will be deposited and maintained in an approved public repository) h. <input checked="" type="checkbox"/> Filing and Examination Fee (\$4,382, made payable to "Treasurer of the United States" (Mail to the Plant Variety Protection Office)				21. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE LIMITED AS TO NUMBER OF CLASSES? <input type="checkbox"/> YES <input type="checkbox"/> NO IF YES, WHICH CLASSES? <input type="checkbox"/> FOUNDATION <input type="checkbox"/> REGISTERED <input type="checkbox"/> CERTIFIED	
23. HAS THE VARIETY (INCLUDING ANY HARVESTED MATERIAL) OR A HYBRID PRODUCED FROM THIS VARIETY BEEN SOLD, DISPOSED OF, TRANSFERRED, OR USED IN THE U. S. OR OTHER COUNTRIES? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO IF YES, YOU MUST PROVIDE THE DATE OF FIRST SALE, DISPOSITION, TRANSFER, OR USE FOR EACH COUNTRY AND THE CIRCUMSTANCES. (Please use space indicated on reverse.)				22. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE LIMITED AS TO NUMBER OF GENERATIONS? <input type="checkbox"/> YES <input type="checkbox"/> NO IF YES, SPECIFY THE NUMBER 1,2,3, etc. FOR EACH CLASS. <input type="checkbox"/> FOUNDATION <input type="checkbox"/> REGISTERED <input type="checkbox"/> CERTIFIED (If additional explanation is necessary, please use the space indicated on the reverse.)	
24. IS THE VARIETY OR ANY COMPONENT OF THE VARIETY PROTECTED BY INTELLECTUAL PROPERTY RIGHT (PLANT BREEDER'S RIGHT OR PATENT)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YES, PLEASE GIVE COUNTRY, DATE OF FILING OR ISSUANCE AND ASSIGNED REFERENCE NUMBER. (Please use space indicated on reverse.)					
25. The owners declare that a viable sample of basic seed of the variety has been furnished with application and will be replenished upon request in accordance with such regulations as may be applicable, or for a tuber propagated variety a tissue culture will be deposited in a public repository and maintained for the duration of the certificate. The undersigned owner(s) is(are) the owner of this sexually reproduced or tuber propagated plant variety, and believe(s) that the variety is new, distinct, uniform, and stable as required in Section 42, and is entitled to protection under the provisions of Section 42 of the Plant Variety Protection Act. Owner(s) is (are) informed that false representation herein can jeopardize protection and result in penalties.					
SIGNATURE OF OWNER (b) (6), (b) (7)(C)		SIGNATURE OF OWNER (b) (6), (b) (7)(C)			
NAME (Please print or type) (b) (6), (b) (7)(C)		NAME (Please print or type) (b) (6), (b) (7)(C)			
CAPACITY OR TITLE Wheat Breeder		DATE Oct. 4, 2007		CAPACITY OR TITLE (b) (6), (b) (7)(C)	
				DATE Oct 8, 2007	



GENERAL INSTRUCTIONS: To be effectively filed with the Plant Variety Protection Office (PVPO), ALL of the following items must be received in the PVPO: (1) Completed application form signed by the owner; (2) completed exhibits A, B, C, E, F; (3) for a tuber reproduced variety, verification that a viable (in the sense that it will reproduce an entire plant) tissue culture will be deposited and maintained in an approved public repository; and (4) payment by credit card or check drawn on a U.S. bank for \$4,382 (\$518 filing fee and \$3,864 examination fee), payable to "Treasurer of the United States" (See Section 97.6 of the Regulations and Rules of Practice). **NEW:** With the application for a seed reproduced variety or by direct deposit soon after filing, the applicant must provide at least 3,000 viable untreated seeds of the variety *per se*, and for a hybrid variety at least 3,000 untreated seeds of each line necessary to reproduce the variety. Partial applications will be held in the PVPO for not more than 90 days; then returned to the applicant as un-filed. Mail application and other requirements to Plant Variety Protection Office, AMS, USDA, Room 401, NAL Building, 10301 Baltimore Avenue, Beltsville, MD 20705-2351. Retain one copy for your files. All items on the face of the application are self explanatory unless noted below. Corrections on the application form and exhibits must be initialed and dated. **DO NOT** use masking materials to make corrections. If a certificate is allowed, you will be requested to send a payment by credit card or check payable to "Treasurer of the United States" in the amount of \$768 for issuance of the certificate. Certificates will be issued to owner, not licensee or agent.

NOTES: It is the responsibility of the applicant/owner to keep the PVPO informed of any changes of address or change of ownership or assignment or owner's representative during the life of the application/certificate. The fees for filing a change of address; owner's representative; ownership or assignment; or any modification of owner's name is specified in Section 97.175 of the regulations. (See Section 101 of the Act, and Sections 97.130, 97.131, 97.175(h) of the Regulations and Rules of Practice.)

Plant Variety Protection Office
Telephone: (301) 504-5518 **FAX:** (301) 504-5291
General E-mail: PVP@mail@usda.gov
Homepage: <http://www.ams.usda.gov/science/pvpo/PVPindex.htm>

SPECIFIC INSTRUCTIONS:

To avoid conflict with other variety names in use, the applicant must check the appropriate recognized authority and provide evidence that the permanent name of the application variety (even if it is a parental, inbred line) has been cleared by the appropriate recognized authority before the Certificate of Protection is issued. For example, for agricultural and vegetable crops, contact: U.S. Department of Agriculture, Agricultural Marketing Service, Livestock and Seed Programs, Seed Regulatory and Testing Branch, 601 Summit Crossing Place, Suite C, Gastonia, North Carolina 28054-2193 Telephone: (704) 810-8870. <http://www.ams.usda.gov/lsg/seed.htm>.

ITEM

- 19a. Give: (1) the genealogy, including public and commercial varieties, lines, or clones used, and the breeding method;
 (2) the details of subsequent stages of selection and multiplication;
 (3) evidence of uniformity and stability; and
 (4) the type and frequency of variants during reproduction and multiplication and state how these variants may be identified
- 19b. Give a summary of the variety's distinctness. Clearly state how this application variety may be distinguished from all other varieties in the same crop. If the new variety is most similar to one variety or a group of related varieties:
 (1) identify these varieties and state all differences objectively;
 (2) attach replicated statistical data for characters expressed numerically and demonstrate that these are clear differences; and
 (3) submit, if helpful, seed and plant specimens or photographs (prints) of seed and plant comparisons which clearly indicate distinctness.
- 19c. Exhibit C forms are available from the PVPO Office for most crops; specify crop kind. Fill in Exhibit C (Objective Description of Variety) form as completely as possible to describe your variety.
- 19d. Optional additional characteristics and/or photographs. Describe any additional characteristics that cannot be accurately conveyed in Exhibit C. Use comparative varieties as is necessary to reveal more accurately the characteristics that are difficult to describe, such as plant habit, plant color, disease resistance, etc.
- 19e. Section 52(5) of the Act requires applicants to furnish a statement of the basis of the applicant's ownership. An Exhibit E form is available from the PVPO.
20. If "Yes" is specified (seed of this variety be sold by variety name only, as a class of certified seed), the applicant **MAY NOT** reverse this affirmative decision after the variety has been sold and so labeled, the decision published, or the certificate issued. However, if "No" has been specified, the applicant may change the choice. (See Regulations and Rules of Practice, Section 97.103).
23. See Sections 41, 42, and 43 of the Act and Section 97.5 of the regulations for eligibility requirements.
24. See Section 55 of the Act for instructions on claiming the benefit of an earlier filing date.

22. CONTINUED FROM FRONT (Please provide a statement as to the limitation and sequence of generations that may be certified.)

23. CONTINUED FROM FRONT (Please provide the date of first sale, disposition, transfer, or use for each country and the circumstances, if the variety (including any harvested material) or a hybrid produced from this variety has been sold, disposed of, transferred, or used in the U.S. or other countries.)

November 8, 2006 USA Certified Seed

24. CONTINUED FROM FRONT (Please give the country, date of filing or issuance, and assigned reference number, if the variety or any component of the variety is protected by intellectual property right (Plant Breeder's Right or Patent).)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotope, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).



Expresso
Hard Red Spring Wheat

#200800002

19.a. Exhibit A. Origin and Breeding History of the Variety

'Expresso' originated from a backcross breeding scheme with the objective of moving stripe rust resistant genes Yr15 and Yr17 into 'Express' background. The donor of Yr15 was the isogenic line of Yr15 in 'Avocet' provided by [REDACTED]. The donor of Lr37/Sr38/Yr17 was the variety Madsen. The genes were introduced separately into Express using 6 backcrosses with Express as the recurrent parent and using molecular markers for selection. The two resulting lines were crossed and the double homozygote line that became 'Expresso' was selected using molecular markers. The pedigree is Express 6*/Yr15 Avocet/Express 6*/Madsen. The crossing and marker assisted selection were performed for WestBred, LLC in the greenhouse by (b)(6), (b)(7)(C) of the (b)(6), (b)(7)(C). In the F3 generation of the final cross, four plants were found to be homozygous for Yr15 and Lr37/Sr38/Yr17. The seed of these four plants were planted in a growth chamber near Bozeman, MT in September of 2004. Seed was harvested from 132 plants in December and planted as plant plots near Yuma, AZ in December of 2004. One hundred twenty plant plots, which were identical and uniform, were harvested, bulked together and designated DA984-034SRR. This seed was used to plant 6 acres near Bozeman, MT in the summer of 2005. The resulting seed was harvested as Breeder Seed and this seed was used to produce Foundation Seed near Woodland, CA in 2006. Certified Seed was first offered for sale November 8, 2006. The breeding method used was backcross Marker Assisted Selection. (MAS)

'Expresso' was tested in replicated yield trials at 9 locations in Central California in 2006 and 2007. (Davis, CA; Dixon, CA; UCD, CA; Colusa, CA; Delta, CA; Corcoran, CA; Five Points, CA; Kern County, CA; and Kings County, CA)

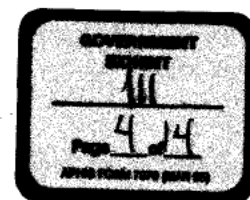
The selection criteria used during the breeding of 'Expresso' was 2 molecular markers associated with Yr15 and the molecular markers associated with Lr37/Sr38/Yr17. The plot selection criteria used in 2005 was a phenotype identical to 'Express'. In 2006 and 2007 the stripe rust resistance of 'Expresso' relative to 'Express' was confirmed by field observation.

'Expresso' has been observed for five generations of reproduction and seed increase and is stable and uniform. 'Expresso' has a tall variant that is 12-30 cms taller that occurs at a frequency of up to .5%. A white seed variant may occur at a frequency of up to .5%. An awnless variant may occur at a frequency of up to .5%. The variants are otherwise identical to the variety in all other characteristics as described in Exhibit C.



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

OR120018_BR_003612



Expresso
Hard Red Spring Wheat

#200800002

19.b. Exhibit B. Statement of Distinctness

'Expresso' most resembles the hard red spring variety 'Express' but differs in that 'Expresso' has the molecular markers associated with the stripe rust resistant genes Yr15 and Lr37/Sr38/Yr17 and is resistance to current stripe rust races in California, while 'Express' does not have the markers and is susceptible to the current stripe rust races in California.

For Yr15 the proximal loci micro-satellite marker used was Xgwm273 and the distal loci micro-satellite marker used was Xbarc8. The 2NS segment contains the genes Lr37/Sr38/Yr17. The two PCR primer pairs used that are specific for 2NS were VENTRIUP and LN2. This is a dominant marker so a CAPS marker was used (primer URIC) to identify the absence of the 2A-allele in the homozygous 2NS plants. The reference is <http://maswheat.ucdavis.edu>.



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

OR120018_BR_003614



Expresso
Hard Red Spring Wheat

#200800002

Table 1. Mean Agronomic Data of 'Expresso' Compared to Check Varieties in 2006 and 2007. UC Davis Regional Common Wheat and Triticale at Sites With High Stripe Rust Infestation. (UC Davis 2006, 2007; Sacramento/ San Joaquin Delta 2006, 2007; Madera 2006; and Colusa 2007)

Variety	Yields in lbs/A	Plant Height cm	Lodging Rating	Heading After 3/1	Test Weight lbs/bu	Protein %	Stripe Rust*
Expresso	5914	104	2.1	44	62.8	14.5	1.1
Express	4980	104	2.2	44	58.5	14.0	5.8
Summit	5541	93	1.0	44	59.1	13.9	6.3

* 1 = none, 2 = trace, 3 = moderately resistant, 4 = moderately susceptible, 5 = susceptible, 9 = dead.

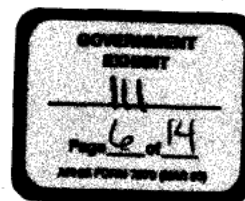
Table 2. Mean Agronomic Data of 'Expresso' Compared to Check Varieties in WestBred, LLC trials in 2006 and 2007 in the Absence of High Levels of Stripe Rust. (Yuma, AZ. 2006, 2007; Corcoran, CA. 2006, 2007; Five Points, CA. 2006, 2007; Dixon, CA. 2006, 2007; and Davis, CA. 2007)

Variety	Yield in lbs/A	Plant Height cm	Days to Head After 3/1	Test Weight lbs/bu	Protein %
Expresso	5455	95	40	63.1	14.9
Express	5607	94	40	63.0	14.3
Summit	5882	87	41	62.2	13.2



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

OR120018_BR_003616



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Expresso
Hard Red Spring Wheat

#200800002

Table 1. Mean Agronomic Data of 'Expresso' Compared to Check Varieties in 2006 and 2007. UC Davis Regional Common Wheat and Triticale at Sites With High Stripe Rust Infestation. (UC Davis 2006, 2007; Sacramento/ San Joaquin Delta 2006, 2007; Madera 2006; and Colusa 2007)

Variety	Yields in lbs/A	Plant Height cm	Lodging Rating	Heading After 3/1	Test Weight lbs/bu	Protein %	Stripe Rust*
Expresso	5914	104	2.1	44	62.8	14.5	1.1
Express	4980	104	2.2	44	58.5	14.0	5.8
Summit	5541	93	1.0	44	59.1	13.9	6.3

* 1 = none, 2 = trace, 3 = moderately resistant, 4 = moderately susceptible, 5 = susceptible, 9 = dead.

Table 2. Mean Agronomic Data of 'Expresso' Compared to Check Varieties in WestBred, LLC trials in 2006 and 2007 in the Absence of High Levels of Stripe Rust. (Yuma, AZ. 2006, 2007; Corcoran, CA. 2006, 2007; Five Points, CA. 2006, 2007; Dixon, CA. 2006, 2007; and Davis, CA. 2007)

Variety	Yield in lbs/A	Plant Height cm	Days to Head After 3/1	Test Weight lbs/bu	Protein %
Expresso	5455	95	40	63.1	14.9
Express	5607	94	40	63.0	14.3
Summit	5882	87	41	62.2	13.2



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

OR120018_BR_003618



5

Expresso
Hard Red Spring Wheat

#200800002

Table 3.

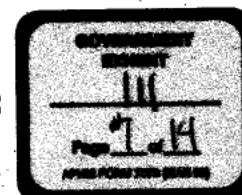
Quality of Expresso compared to Express and Blanca Grande				
	California Extension Trials		California Wheat Collaborative Trial	
	Expresso	Express	Expresso	Blanca Grande
% Protein	16.0	16.2	16.1	15.1
Flour Yield	65.0	64.4	63.5	63.1
Falling number	473	468	453	371
Wet Gluten	35.8	35.6	32.9	30.0
Farinograph Absorption	61.8	61.6	62.2	61.5
Arrival	3.0	3.0	6.00	17.5
Mix tolerance	22.5	26.0	16.0	12.5
MTI	20	20	10	15
Bread Volume cc	955	1000	1005	945
Texture rating	S	S	S	S
Bake Score	5	5	5	5

*Quality Data provided by the California Wheat Commission



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

OR120018_BR_003620



6

Expresso
Hard Red Spring Wheat

#200800002

**Table 4 Quality of Expresso Compared to Express and Blanca Grande
Cargill Bake Lab Analysis.**

Trait	Expresso	Express	Blanca Grande
% Protein	14.9	13.6	12.8
Loaf Volume cc	900	933	933
Crumb Grain Rating	5	5	10
Crumb Texture Rating	10	10	10
Crumb Color Rating	5	5	5
Dough Handling Rating	5	5	10
Mix Tolerance Rating	5	10	5
Bake Score	53	58	63



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

OR120018_BR_003622



According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 2.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, S.W., Washington, D.C. 20250-0410, or call (800) 795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer.

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY
PLANT VARIETY PROTECTION OFFICE
BELTSVILLE, MD 20705

Exhibit C

OBJECTIVE DESCRIPTION OF VARIETY
Wheat (*Triticum* spp.)

NAME OF APPLICANT (S) WestBred, LLC	TEMPORARY OR EXPERIMENTAL DESIGNATION DA984-034SRR	VARIETY NAME Expresso
ADDRESS (Street and No. or RD No., City, State, Zip Code and Country) 81 Timberline Drive Bozeman, MT 59718		FOR OFFICIAL USE ONLY PVPO NUMBER #200800002

PLEASE READ ALL INSTRUCTIONS CAREFULLY:

Place the appropriate number that describes the varietal character of this variety in the boxes below. Place a zero in the first box (e.g., or) when number is either 99 or less or 9 or less respectively. Data for quantitative plant characters should be based on a minimum of 100 plants. Comparative data should be determined from varieties entered in the same trial. Royal Horticultural Society or any recognized color standard may be used to determine plant colors; designate system used: Munsell Color Chart. Please answer all questions for your variety; lack of response may delay progress of your application.

1. KIND:

- ☒ 1 = Common
2 = Durum
3 = Club
4 = Other (Specify) _____

2. VERNALIZATION:

- ☐ 1 = Spring
2 = Winter
3 = Other (Specify) _____

3. COLEOPTILE ANTHOCYANIN:

- ☐ 1 = Absent 2 = Present

4. JUVENILE PLANT GROWTH:

- ☐ 1 = Prostrate 2 = Semi-Erect 3 = Erect

5. PLANT COLOR: (boot stage)

- ☐ 1 = Yellow-Green
2 = Green
3 = Blue-Green

6. FLAG LEAF: (boot stage)

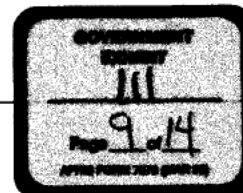
- ☐ 1 = Erect 2 = Recurved
☐ 1 = Not Twisted 2 = Twisted
☐ 1 = Wax Absent 2 = Wax Present

7. EAR EMERGENCE:

- Number of Days (Average)
 Number of Days Earlier Than * _____
Same As * Express
 Number of Days Later Than * _____
*Relative to a PVPO-Approved Commercial Variety Grown in the Same Trial

8. ANTER COLOR:

- ☐ 1 = Yellow 2 = Purple



9. PLANT HEIGHT: (from soil to top of head, excluding awns)

1 0 4

cm (Average)

cm Taller Than

cm

Same As

Express

cm Shorter Than

10. STEM:

A. ANTHOCYANIN

1

1 = Absent 2 = Present

B. WAXY BLOOM

2

1 = Absent 2 = Present

C. HAIRINESS (last internode of rachis)

2

1 = Absent 2 = Present

D. INTERNODE

1

1 = Hollow 2 = Semi-Solid 3 = Solid

5

Number of Nodes

E. PEDUNCLE

1

1 = Erect 2 = Recurved 3 = Semi-Erect

1 4

cm Length

F. AURICLE

1

Anthocyanin: 1 = Absent 2 = Present

2

Hair: 1 = Absent 2 = Present

11. HEAD: (At Maturity)

A. DENSITY

1

1 = Lax
2 = Middense (Laxidense)
3 = Dense

B. SHAPE

2

1 = Tapering
2 = Strap
3 = Clavate
4 = Other (Specify)

C. CURVATURE

1

1 = Erect
2 = Inclined
3 = Recurved

D. AWNEDNESS

4

1 = Awnless
2 = Apically Awnletted
3 = Awnletted
4 = Awned

12. GLUMES: (At Maturity)

A. COLOR

1

1 = White
2 = Tan
3 = Other (Specify)

B. SHOULDER

2

1 = Wanting 2 = Oblique
3 = Rounded 4 = Square
5 = Elevated 6 = Apiculate
7 = Other (Specify)

C. SHOULDER WIDTH

2

1 = Narrow
2 = Medium
3 = Wide

D. BEAK

3

1 = Obtuse
2 = Acute
3 = Acuminate

E. BEAK WIDTH

2

1 = Narrow
2 = Medium
3 = Wide

F. GLUME LENGTH

3

1 = Short (ca. 7 mm)
2 = Medium (ca. 8 mm)
3 = Long (ca. 9 mm)

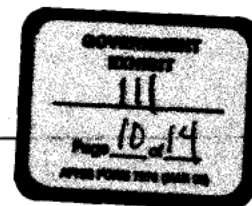
G. WIDTH

3

1 = Narrow (ca. 3 mm)
2 = Medium (ca. 3.5 mm)
3 = Wide (ca. 4 mm)

H. PUBESCENCE

2

1 = Not Present
2 = Present

13. SEED:

A. SHAPE

- ☐ 3 1 = Ovate
2 = Oval
3 = Elliptical

B. CHEEK

- ☐ 1 1 = Rounded
2 = Angular

C. BRUSH

- ☐ 2 1 = Short 1 = Not Collared
2 = Medium 2 = Collared
3 = Long

D. CREASE

- ☐ 1 1 = Width 60% or less of Kernel
2 = Width 80% or less of Kernel
3 = Width Nearly as Wide as Kernel
- ☐ 2 1 = Depth 20% or less of Kernel
2 = Depth 35% or less of Kernel
3 = Depth 50% or less of Kernel

E. COLOR

- ☐ 3 1 = White
2 = Amber
3 = Red
4 = Other (Specify) _____

F. TEXTURE

- ☐ 1 1 = Hard
2 = Soft
3 = Other (Specify) _____

G. PHENOL REACTION (See Instructions)

- ☐ 4 1 = Ivory 4 = Dark Brown
2 = Fawn 5 = Black
3 = Light Brown

H. SEED WEIGHT

- ☐ 4 ☐ 5 g/1000 Seed (whole number only)

I. GERM SIZE

- ☐ 2 1 = Small
2 = Midsize
3 = Large

14. DISEASE: PLEASE INDICATE THE SPECIFIC RACE OR STRAIN TESTED

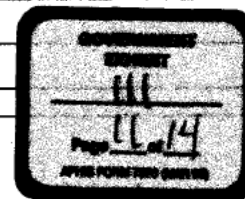
(0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

- | | |
|---|---|
| <input type="checkbox"/> 0 Stem Rust (<i>Puccinia graminis</i> f. sp. <i>tritici</i>) | <input type="checkbox"/> 0 Leaf Rust (<i>Puccinia recondita</i> f. sp. <i>tritici</i>) |
| <input type="checkbox"/> 2 Stripe Rust (<i>Puccinia striiformis</i>) | <input type="checkbox"/> 0 Loose Smut (<i>Ustilago tritici</i>) |
| <input type="checkbox"/> 0 Tan Spot (<i>Pyrenophora tritici-repentis</i>) | <input type="checkbox"/> 0 Flag Smut (<i>Urocystis agropyri</i>) |
| <input type="checkbox"/> 0 Halo Spot (<i>Selenophoma donacis</i>) | <input type="checkbox"/> 0 Common Bunt (<i>Tilletia tritici</i> or <i>T. laevis</i>) |
| <input type="checkbox"/> 0 Septoria nodorum (Glume Blotch) | <input type="checkbox"/> 0 Dwarf Bunt (<i>Tilletia controversa</i>) |
| <input type="checkbox"/> 0 Septoria avenae (Speckled Leaf Disease) | <input type="checkbox"/> 0 Karnal Bunt (<i>Tilletia indica</i>) |
| <input type="checkbox"/> 4 Septoria tritici (Speckled Leaf Blotch) | <input type="checkbox"/> 0 Powdery Mildew (<i>Erysiphe graminis</i> f. sp. <i>tritici</i>) |
| <input type="checkbox"/> 0 Scab (<i>Fusarium</i> spp.) | <input type="checkbox"/> 0 "Snow Molds" |
| <input type="checkbox"/> 0 "Black Point" (Kernel Smudge) | <input type="checkbox"/> 0 Common Root Rot (<i>Fusarium</i> , <i>Cochliobolus</i> and <i>Bipolaris</i> spp.) |
| <input type="checkbox"/> 1 Barley Yellow Dwarf Virus (BYDV) | <input type="checkbox"/> 0 Rhizoctonia Root Rot (<i>Rhizoctonia solani</i>) |
| <input type="checkbox"/> 0 Soilborne Mosaic Virus (SBMV) | <input type="checkbox"/> 0 Black Chaff (<i>Xanthomonas campestris</i> pv. <i>translucens</i>) |
| <input type="checkbox"/> 0 Wheat Yellow (Spindle Streak) Mosaic Virus | <input type="checkbox"/> 0 Bacterial Leaf Blight (<i>Pseudomonas syringae</i> pv. <i>syringae</i>) |
| <input type="checkbox"/> 0 Wheat Streak Mosaic Virus (WSMV) | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |

15. INSECT: (0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

PLEASE SPECIFY BIOTYPE (where needed)

- | | |
|--|--|
| <input type="checkbox"/> 0 Hessian Fly (<i>Mayetiola destructor</i>) | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> 0 Stem Sawfly (<i>Cephus</i> spp.) | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> 0 Cereal Leaf Beetle (<i>Oulema melanopa</i>) | <input type="checkbox"/> Other (Specify) _____ |



#200800002

Exhibit C (Wheat)

15. INSECT: (continued) (0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

PLEASE SPECIFY BIOTYPE (Where Needed)

☐

Russian Aphid (*Diuraphis noxia*)

☐

Other (Specify) _____

☐

Greenbug (*Schizaphis graminum*)

☐

Other (Specify) _____

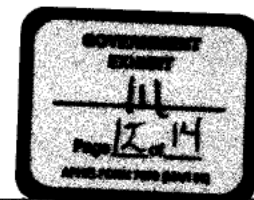
☐

Aphids

☐

Other (Specify) _____

16. ADDITIONAL INFORMATION ON ANY ITEM ABOVE, OR GENERAL COMMENTS:



U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE**EXHIBIT E**
STATEMENT OF THE BASIS OF OWNERSHIP

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). The information is held confidential until the certificate is issued (7 U.S.C. 2426).

1. NAME OF APPLICANT(S) WestBred, LLC	2. TEMPORARY DESIGNATION OR EXPERIMENTAL NUMBER DA984-034RR	3. VARIETY NAME Expresso
4. ADDRESS (Street and No., or R.F.D. No., City, State, and ZIP, and Country) 81 Timberline Drive Bozeman, MT 59718	5. TELEPHONE (Include area code) (406) 587-1218	6. FAX (Include area code) (406) 587-8247
7. PVPO NUMBER #200800002		

8. Does the applicant own all rights to the variety? Mark an "X" in the appropriate block. If no, please explain. ☒ YES ☐ NO9. Is the applicant (individual or company) a U.S. national or a U.S. based company? If no, give name of country. ☒ YES ☐ NO10. Is the applicant the original owner? ☒ YES ☐ NO If no, please answer one of the following:

a. If the original rights to variety were owned by individual(s), is (are) the original owner(s) a U.S. National(s)?

☐ YES ☐ NO If no, give name of country

b. If the original rights to variety were owned by a company(ies), is (are) the original owner(s) a U.S. based company?

☐ YES ☐ NO If no, give name of country

11. Additional explanation on ownership (Trace ownership from original breeder to current owner. Use the reverse for extra space if needed):

PLEASE NOTE:

Plant variety protection can only be afforded to the owners (not licensees) who meet the following criteria:

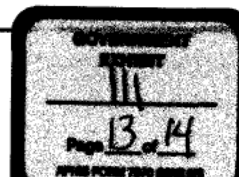
1. If the rights to the variety are owned by the original breeder, that person must be a U.S. national, national of a UPOV member country, or national of a country which affords similar protection to nationals of the U.S. for the same genus and species.
2. If the rights to the variety are owned by the company which employed the original breeder(s), the company must be U.S. based, owned by nationals of a UPOV member country, or owned by nationals of a country which affords similar protection to nationals of the U.S. for the same genus and species.
3. If the applicant is an owner who is not the original owner, both the original owner and the applicant must meet one of the above criteria.

The original breeder/owner may be the individual or company who directed the final breeding. See Section 41(a)(2) of the Plant Variety Protection Act for definitions.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 0.1 hour per response, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW, Washington, D.C. 20250-9410 or call (202) 720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.



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According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW, Washington, DC 20250-9410 or call 202-720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY
PLANT VARIETY PROTECTION OFFICE
BELTSVILLE, MD 20705

EXHIBIT F
DECLARATION REGARDING DEPOSIT

<p>NAME OF OWNER (S)</p> <p>WestBred, LLC</p>	<p>ADDRESS (Street and No. or RD No., City, State, and Zip Code and Country)</p> <p>WestBred, LLC P.O. Box 6904 Yuma, AZ 85366</p>	<p>TEMPORARY OR EXPERIMENTAL DESIGNATION</p> <p>DA984-034SRR</p>
<p>NAME OF OWNER REPRESENTATIVE (S)</p> <p>(b) (6), (b) (7)(C)</p>	<p>ADDRESS (Street and No. or RD No., City, State, and Zip Code and Country)</p> <p>WestBred, LLC P.O. Box 6904 Yuma, AZ 85366</p>	<p>VARIETY NAME</p> <p>Espresso</p> <p>FOR OFFICIAL USE ONLY</p> <p>PVPO NUMBER</p> <p>#200800002</p>

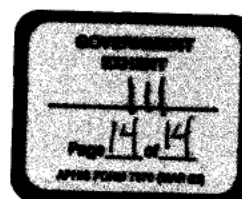
I do hereby declare that during the life of the certificate a viable sample of propagating material of the subject variety will be deposited, and replenished as needed periodically, in a public repository in the United States in accordance with the regulations established by the Plant Variety Protection Office.

(b) (6), (b) (7)(C)

Signature

October 4, 2007

Date



No.

200700017

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS, SHALL COME:

West Bred, LLC

Whereas, THERE HAS BEEN PRESENTED TO THE

Secretary of Agriculture

AN APPLICATION REQUESTING A CERTIFICATE OF PROTECTION FOR AN ALLEGED DISTINCT VARIETY OF SEXUALLY REPRODUCED, OR TUBER PROPAGATED PLANT, THE NAME AND DESCRIPTION OF WHICH ARE CONTAINED IN THE APPLICATION AND EXHIBITS, A COPY OF WHICH IS HEREUNTO ANNEXED AND MADE A PART HEREOF, AND THE VARIOUS REQUIREMENTS OF LAW IN SUCH CASES MADE AND PROVIDED HAVE BEEN COMPLIED WITH, AND THE TITLE THERETO IS, FROM THE RECORDS OF THE PLANT VARIETY PROTECTION OFFICE, IN THE APPLICANT(S) INDICATED IN THE SAID COPY, AND WHEREAS, UPON DUE EXAMINATION MADE, THE SAID APPLICANT(S) IS (ARE) ADJUDGED TO BE ENTITLED TO A CERTIFICATE OF PLANT VARIETY PROTECTION UNDER THE LAW.

NOW, THEREFORE, THIS CERTIFICATE OF PLANT VARIETY PROTECTION IS TO GRANT UNTO THE SAID APPLICANT(S) AND THE SUCCESSORS, HEIRS OR ASSIGNS OF THE SAID APPLICANT(S) FOR THE TERM OF TWENTY YEARS FROM THE DATE OF THIS GRANT, SUBJECT TO THE PAYMENT OF THE REQUIRED FEES AND PERIODIC DEPOSITMENT OF VIABLE BASIC SEED OF THE VARIETY IN A PUBLIC REPOSITORY AS PROVIDED BY LAW, THE SAID APPLICANT(S) TO EXCLUDE OTHERS FROM SELLING THE VARIETY, OR OFFERING IT FOR SALE, OR REPRODUCING IT, OR PROPAGATING IT, OR EXPORTING IT, OR CONDITIONING IT FOR PROPAGATION, OR STOCKING IT FOR ANY OF THE FOREGOING PURPOSES, OR USING IT IN PRODUCING A HYBRID OR DIFFERENT VARIETY THEREFROM, TO THE EXTENT PROVIDED BY THE PLANT VARIETY PROTECTION ACT. (84 STAT. 1542, AS AMENDED, 7 U.S.C. 2321 ET SEQ.)

WHEAT, COMMON

'Solano'

In Testimony Whereof, I have hereunto set my hand and caused the seal of the Plant Variety Protection Office to be affixed at the City of Washington, D.C. this ninth day of March, in the year two thousand and seven.

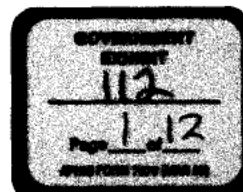
Attest:



Commissioner
Plant Variety Protection Office
Agricultural Marketing Service



Secretary of Agriculture



U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY - PLANT VARIETY PROTECTION OFFICEAPPLICATION FOR PLANT VARIETY PROTECTION CERTIFICATE
(Instructions and information collection burden statement on reverse)

The following statements are made in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the Paperwork Reduction Act (PRA) of 1995.

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). Information is held confidential until certificate is issued (7 U.S.C. 2426).

1. NAME OF OWNER WestBred, LLC		2. TEMPORARY DESIGNATION OR EXPERIMENTAL NAME DA900-229	3. VARIETY NAME Solano
4. ADDRESS (Street and No., or R.F.D. No., City, State, and ZIP Code, and Country) 81 Timberline Drive Bozeman, MT 59718		5. TELEPHONE (include area code) 406-587-1218	FOR OFFICIAL USE ONLY PVPO NUMBER 2007 00017 FILING DATE OCTOBER 23, 2006
		6. FAX (include area code) 406-586-8247	
7. IF THE OWNER NAMED IS NOT A "PERSON", GIVE FORM OF ORGANIZATION (corporation, partnership, association, etc.) WestBred, LLC	8. IF INCORPORATED, GIVE STATE OF INCORPORATION Arizona	9. DATE OF INCORPORATION August 4, 2003	
10. NAME AND ADDRESS OF OWNER REPRESENTATIVE(S) TO SERVE IN THIS APPLICATION. (First person listed will receive all papers) (b)(6), (b)(7)(C) WestBred, LLC P.O. Box 6904 Yuma, Az 85366			F E E S R E C E I V E D FILING AND EXAMINATION FEES: \$ 4,382.00 DATE 10/23/06 CERTIFICATION FEE: \$ 768.00 DATE 2/15/07

11. TELEPHONE (include area code) (b)(6), (b)(7)(C)	12. FAX (include area code) (b)(6), (b)(7)(C)	13. E-MAIL (b)(6), (b)(7)(C)
14. CROP KIND (Common Name) Common Wheat	16. FAMILY NAME (Botanical) Poaceae	18. DOES THE VARIETY CONTAIN ANY TRANSGENES? (OPTIONAL) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF SO, PLEASE GIVE THE ASSIGNED USDA-APHIS REFERENCE NUMBER FOR THE APPROVED PETITION TO DEREGULATE THE GENETICALLY MODIFIED PLANT FOR COMMERCIALIZATION.
15. GENUS AND SPECIES NAME OF CROP Triticum Aestivum	17. IS THE VARIETY A FIRST GENERATION HYBRID? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	20. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE SOLD AS A CLASS OF CERTIFIED SEED? (See Section 83(a) of the Plant Variety Protection Act) <input type="checkbox"/> YES (If "yes", answer items 21 and 22 below) <input checked="" type="checkbox"/> NO (If "no", go to item 23)
19. CHECK APPROPRIATE BOX FOR EACH ATTACHMENT SUBMITTED (Follow instructions on reverse) a. <input checked="" type="checkbox"/> Exhibit A. Origin and Breeding History of the Variety b. <input checked="" type="checkbox"/> Exhibit B. Statement of Distinctness c. <input checked="" type="checkbox"/> Exhibit C. Objective Description of Variety d. <input type="checkbox"/> Exhibit D. Additional Description of the Variety (Optional) e. <input checked="" type="checkbox"/> Exhibit E. Statement of the Basis of the Owner's Ownership f. <input checked="" type="checkbox"/> Exhibit F. Declaration Regarding Deposit g. <input checked="" type="checkbox"/> Voucher Sample (3,000 viable untreated seeds or, for tuber propagated varieties, verification that tissue culture will be deposited and maintained in an approved public repository) h. <input checked="" type="checkbox"/> Filing and Examination Fee (\$4,382), made payable to "Treasurer of the United States" (Mail to the Plant Variety Protection Office)		21. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE LIMITED AS TO NUMBER OF CLASSES? <input type="checkbox"/> YES <input type="checkbox"/> NO IF YES, WHICH CLASSES? <input type="checkbox"/> FOUNDATION <input type="checkbox"/> REGISTERED <input type="checkbox"/> CERTIFIED
23. HAS THE VARIETY (INCLUDING ANY HARVESTED MATERIAL) OR A HYBRID PRODUCED FROM THIS VARIETY BEEN SOLD, DISPOSED OF, TRANSFERRED, OR USED IN THE U. S. OR OTHER COUNTRIES? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO November 10, 2005 IF YES, YOU MUST PROVIDE THE DATE OF FIRST SALE, DISPOSITION, TRANSFER, OR USE FOR EACH COUNTRY AND THE CIRCUMSTANCES. (Please use space indicated on reverse.)		22. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE LIMITED AS TO NUMBER OF GENERATIONS? <input type="checkbox"/> YES <input type="checkbox"/> NO IF YES, SPECIFY THE NUMBER 1,2,3, etc. FOR EACH CLASS. <input type="checkbox"/> FOUNDATION <input type="checkbox"/> REGISTERED <input type="checkbox"/> CERTIFIED (If additional explanation is necessary, please use the space indicated on the reverse.)
24. IS THE VARIETY OR ANY COMPONENT OF THE VARIETY PROTECTED BY INTELLECTUAL PROPERTY RIGHT (PLANT BREEDER'S RIGHT OR PATENT)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YES, PLEASE GIVE COUNTRY, DATE OF FILING OR ISSUANCE AND ASSIGNED REFERENCE NUMBER. (Please use space indicated on reverse.)		

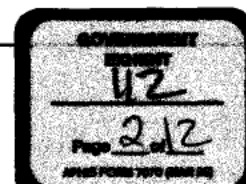
25. The owners declare that a viable sample of basic seed of the variety has been furnished with application and will be replenished upon request in accordance with such regulations as may be applicable, or for a tuber propagated variety a tissue culture will be deposited in a public repository and maintained for the duration of the certificate.

The undersigned owner(s) is(are) the owner of this sexually reproduced or tuber propagated plant variety, and believe(s) that the variety is new, distinct, uniform, and stable as required in Section 42, and is entitled to protection under the provisions of Section 42 of the Plant Variety Protection Act.

Owner(s) is (are) informed that false representation herein can jeopardize protection and result in penalties.

NAME (Please print or type) (b)(6), (b)(7)(C)		SIGNATURE OF OWNER (b)(6), (b)(7)(C)	
CAPACITY OR TITLE Wheat Breeder		CAPACITY OR TITLE (b)(6), (b)(7)(C)	
DATE Oct. 17, 2006		DATE Oct 20, 2006	

(See reverse for instructions and information collection burden statement)



GENERAL INSTRUCTIONS: To be effectively filed with the Plant Variety Protection Office (PVPO), ALL of the following items must be received in the PVPO: (1) Completed application form signed by the owner; (2) completed exhibits A, B, C, E, F; (3) for a tuber reproduced variety, verification that a viable (in the sense that it will reproduce an entire plant) tissue culture will be deposited and maintained in an approved public repository; and (4) payment by credit card or check drawn on a U.S. bank for \$4,382 (\$518 filing fee and \$3,864 examination fee), payable to "Treasurer of the United States" (See Section 97.6 of the Regulations and Rules of Practice). **NEW:** With the application for a seed reproduced variety or by direct deposit soon after filing, the applicant must provide at least 3,000 viable untreated seeds of the variety per se, and for a hybrid variety at least 3,000 untreated seeds of each line necessary to reproduce the variety. Partial applications will be held in the PVPO for not more than 90 days; then returned to the applicant as un-filed. Mail application and other requirements to Plant Variety Protection Office, AMS, USDA, Room 401, NAL Building, 10301 Baltimore Avenue, Beltsville, MD 20705-2351. **Retain one copy for your files.** All items on the face of the application are self explanatory unless noted below. Corrections on the application form and exhibits must be initialed and dated. **DO NOT** use masking materials to make corrections. If a certificate is allowed, you will be requested to send a payment by credit card or check payable to "Treasurer of the United States" in the amount of \$768 for issuance of the certificate. Certificates will be issued to owner, not licensee or agent.

NOTES: It is the responsibility of the applicant/owner to keep the PVPO informed of any changes of address or change of ownership or assignment or owner's representative during the life of the application/certificate. The fees for filing a change of address; owner's representative; ownership or assignment; or any modification of owner's name is specified in Section 97.175 of the regulations. (See Section 101 of the Act, and Sections 97.130, 97.131, 97.175(h) of the Regulations and Rules of Practice.)

Plant Variety Protection Office
Telephone: (301) 504-5518 FAX: (301) 504-5291
General E-mail: PVPOmail@usda.gov
Homepage: <http://www.ams.usda.gov/science/pvpo/PVPindex.htm>

2007 00017

SPECIFIC INSTRUCTIONS:

To avoid conflict with other variety names in use, the applicant must check the appropriate recognized authority and provide evidence that the permanent name of the application variety (even if it is a parental, inbred line) has been cleared by the appropriate recognized authority before the Certificate of Protection is issued. For example, for agricultural and vegetable crops, contact: U.S. Department of Agriculture, Agricultural Marketing Service, Livestock and Seed Programs, Seed Regulatory and Testing Branch, 801 Summit Crossing Place, Suite C, Gastonia, North Carolina 28054-2193 Telephone: (704) 810-8870. <http://www.ams.usda.gov/lsg/seed.htm>.

ITEM

- 19a. Give:
- (1) the genealogy, including public and commercial varieties, lines, or clones used, and the breeding method;
 - (2) the details of subsequent stages of selection and multiplication;
 - (3) evidence of uniformity and stability; and
 - (4) the type and frequency of variants during reproduction and multiplication and state how these variants may be identified
- 19b. Give a summary of the variety's distinctness. Clearly state how this application variety may be distinguished from all other varieties in the same crop. If the new variety is most similar to one variety or a group of related varieties:
- (1) identify these varieties and state all differences objectively;
 - (2) attach replicated statistical data for characters expressed numerically and demonstrate that these are clear differences; and
 - (3) submit, if helpful, seed and plant specimens or photographs (prints) of seed and plant comparisons which clearly indicate distinctness.
- 19c. Exhibit C forms are available from the PVPO Office for most crops; specify crop kind. Fill in Exhibit C (Objective Description of Variety) form as completely as possible to describe your variety.
- 19d. Optional additional characteristics and/or photographs. Describe any additional characteristics that cannot be accurately conveyed in Exhibit C. Use comparative varieties as is necessary to reveal more accurately the characteristics that are difficult to describe, such as plant habit, plant color, disease resistance, etc.
- 19e. Section 52(5) of the Act requires applicants to furnish a statement of the basis of the applicant's ownership. An Exhibit E form is available from the PVPO.
20. If "Yes" is specified (seed of this variety be sold by variety name only, as a class of certified seed), the applicant **MAY NOT** reverse this affirmative decision after the variety has been sold and so labeled, the decision published, or the certificate issued. However, if "No" has been specified, the applicant may change the choice. (See Regulations and Rules of Practice, Section 97.103).
23. See Sections 41, 42, and 43 of the Act and Section 97.5 of the regulations for eligibility requirements.
24. See Section 55 of the Act for instructions on claiming the benefit of an earlier filing date.

22. CONTINUED FROM FRONT (Please provide a statement as to the limitation and sequence of generations that may be certified.)

23. CONTINUED FROM FRONT (Please provide the date of first sale, disposition, transfer, or use for each country and the circumstances, if the variety (including any harvested material) or a hybrid produced from this variety has been sold, disposed of, transferred, or used in the U.S. or other countries.)

November 10, 2005; United States of America; Certified Seed

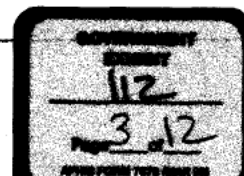
24. CONTINUED FROM FRONT (Please give the country, date of filing or issuance, and assigned reference number, if the variety or any component of the variety is protected by intellectual property right (Plant Breeder's Right or Patent).)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 1.4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, S.W., Washington, D.C. 20250-9410, or call (800) 795-3272 (voice) or (202) 720-6382 (TDD). USDA is an equal opportunity provider and employer.

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2

200700017

‘Solano’
Hard Red Spring Wheat

19.a. Exhibit A. Origin and Breeding History (Revised)

‘Solano’ was developed by WestBred, LLC from a cross made in 1998 with the pedigree of DA993-191/Express. DA993-191 has the pedigree of Serra/Express. The breeding method used was selected single-spike descent modified pedigree.

The F1 increase from which ‘Solano’ originated was grown near Bozeman, MT, in the summer of 1998. The F2 generation was grown near Yuma, AZ, in the winter growing season of 1998-1999. Individual spikes were selected and bulked together to plant an F3 population near Bozeman, MT, in the spring of 1999. Individual spikes were selected and planted as F4 spike-rows near Davis, CA, in 1999-2000. Individual plants were selected from disease-resistant rows and grown as F5 plots near Bozeman, MT in 2000. One plant plot, designated ‘DA900-229,’ was used to plant replicated yield trials at three locations in the 2000-2001 winter growing season. Replicated yield trials were conducted at four locations in 2001 through 2006. (Davis, CA; Dixon, CA; Hanford, CA and Five Points, CA)

The selection criteria used during the breeding of ‘Solano’ were as follows:

- F1 None, Bulk harvest
- F2 Large spikes, semidwarf growth habit, and robust plants
- F3 Same as F2
- F4 Large spikes, stripe rust resistance, leaf rust resistance, Septoria tritici resistance
- F5 None, seed increase
- F6 Plump seed, high test weight, high % protein, high S.D.S. sedimentation, strong mixograph and lodging resistance

In 2002, thirty two spikes were selected and grown as spike rows near Yuma, AZ. In May 2003 twenty one rows that were uniform and identical were bulked together. This seed was used to produce breeder seed near Bozeman, MT, in 2003. Foundation and Registered seed were produced in California in 2004 and 2005 respectively. Certified ‘Solano’ was first sold on November 10, 2005.

‘Solano’ has been observed for six generations of reproduction and seed increase and is stable and uniform

Solano has a tall variant that is 12cm to 30 cm taller that occurs at a frequency of up to .4%. An awnless variant occurs at a frequency of up to .4%. The variants are otherwise identical to the variety in all other characteristics.

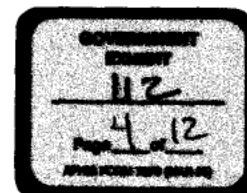
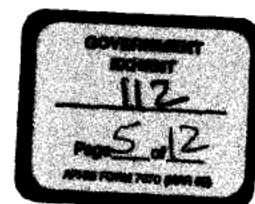


Table 2.

MILLING, MIXING & BAKING QUALITY**

		Solano	Express	Summit
% Protein		14.5	14.0	13.5
% Ash		1.4	1.6	1.53
Falling number		437	382	431
% Extraction		68.0	66.7	69.8
Wet Gluten		38.6	35.2	32.6
Farinograph	Absorption	67.3	67.5	65.2
	Arrival	5.1	4.6	4.4
	Mixing Tolerance	12.9	9.1	12.4
	MTI	28	34	36
Baking	Loaf Volume	964	905	898
	Specific Volume	6.5	6.3	6.2
	Score	4.8	4	3.5

**Average of 4
locations
Analysis performed by
the California Wheat
Commission



19.b.Exhibit B. Statement of Distinctness

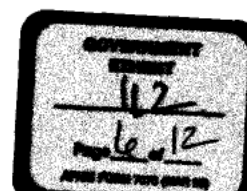
'Solano' most resembles the hard red spring wheat variety 'Express'. 'Solano' can be distinguished from 'Express' in that 'Express' has oblique glume shoulders while 'Solano' has elevated glume shoulders.

The above comparisons, along with the complete Objective Description (Exhibit C) show 'Solano' to be a novel variety of hard red spring wheat.

Table 1. Agronomic Characteristics of 'Solano' Compared to Check Varieties in WestBred, LLC Trials in California. (Mean of 20 location/years form 2001-2006)

Entry	Yield	Test	Protein	S.D.S.	Plant	Days to	Lodging	Stripe	Septoria
	Lbs/A	Weight	Percent	Sed	Height	Head	Percent	Rust	tritici
		(lb)			(cm)	After 3/1		Rating*	Rating*
Solano	5848	62.9	14.1	111	89	28	20	1.7	0.7
Express	5318	61.8	14.0	109	97	28	44	3.6	1.8
RSI-5	5465	62.0	12.7	85	98	27	60	4.1	1.3
Summit	6147	61.8	13.3	114	88	28	0	2.0	4.2

* 0 = None, 1 = Trace, 3 = Moderately resistant, 5 = Moderately susceptible, 7 = Susceptible, 9 = Dead



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U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY
PLANT VARIETY PROTECTION OFFICE
BELTSVILLE, MD 20705

Exhibit C

OBJECTIVE DESCRIPTION OF VARIETY
Wheat (*Triticum* spp.)

NAME OF APPLICANT (S)	TEMPORARY OR EXPERIMENTAL DESIGNATION	VARIETY NAME
WestBred, LLC	DA900-229	Solano
ADDRESS (Street and No. or RD No., City, State, Zip Code and Country)		FOR OFFICIAL USE ONLY
81 Timberline Drive Bozeman, MT 59718		PVPO NUMBER 2007 00017

PLEASE READ ALL INSTRUCTIONS CAREFULLY:

Place the appropriate number that describes the varietal character of this variety in the boxes below. Place a zero in the first box (e.g., 0 9 9 or 0 9) when number is either 99 or less or 9 or less respectively. Data for quantitative plant characters should be based on a minimum of 100 plants. Comparative data should be determined from varieties entered in the same trial. Royal Horticultural Society or any recognized color standard may be used to determine plant colors; designate system used: Munsell Color Chart. Please answer all questions for your variety; lack of response may delay progress of your application.

1. KIND:

1

- 1 = Common
2 = Durum
3 = Club
4 = Other (Specify) _____

2. VERNALIZATION:

1

- 1 = Spring
2 = Winter
3 = Other (Specify) _____

3. COLEOPTILE ANTHOCYANIN:

1

- 1 = Absent 2 = Present

4. JUVENILE PLANT GROWTH:

3

- 1 = Prostrate 2 = Semi-Erect 3 = Erect

5. PLANT COLOR: (boot stage)

2

- 1 = Yellow-Green
2 = Green
3 = Blue-Green

6. FLAG LEAF: (boot stage)

1

- 1 = Erect 2 = Recurved
2 = Not Twisted 2 = Twisted
2 = Wax Absent 2 = Wax Present

7. EAR EMERGENCE:

129

Number of Days (Average)

Number of Days Earlier Than *

Same As

* Express

Number of Days Later Than *

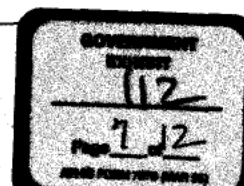
*Relative to a PVPO-Approved Commercial Variety Grown in the Same Trial

8. ANTER COLOR:

1

- 1 = Yellow 2 = Purple

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6e

9. PLANT HEIGHT: (from soil to top of head, excluding awns)

0 89

cm (Average)

cm

cm Taller Than

Same As

0 8

cm Shorter Than Express

200700017

10. STEM:

A. ANTHOCYANIN

1

1 = Absent 2 = Present

B. WAXY BLOOM

2

1 = Absent 2 = Present

C. HAIRINESS (last internode of rachis)

2

1 = Absent 2 = Present

D. INTERNODE

1

1 = Hollow 2 = Semi-Solid 3 = Solid

4

Number of Nodes

E. PEDUNCLE

1

1 = Erect 2 = Recurved 3 = Semi-Erect

3 0

cm Length

F. AURICLE

1

Anthocyanin: 1 = Absent 2 = Present

2

Hair: 1 = Absent 2 = Present

11. HEAD: (At Maturity)

A. DENSITY

1

1 = Lax
2 = Middense (Laxdense)
3 = Dense

B. SHAPE

2

1 = Tapering
2 = Strap
3 = Clavate
4 = Other (Specify)

C. CURVATURE

2

1 = Erect
2 = Inclined
3 = Recurved

D. AWNEDNESS

4

1 = Awnless
2 = Apically Awnletted
3 = Awnletted
4 = Awned

12. GLUMES: (At Maturity)

A. COLOR

1

1 = White
2 = Tan
3 = Other (Specify)

B. SHOULDER

5

1 = Wanting 2 = Oblique
3 = Rounded 4 = Square
5 = Elevated 6 = Apiculate
7 = Other (Specify)

C. SHOULDER WIDTH

1

1 = Narrow
2 = Medium
3 = Wide

D. BEAK

3

1 = Obtuse
2 = Acute
3 = Acuminate

E. BEAK WIDTH

2

1 = Narrow
2 = Medium
3 = Wide

F. GLUME LENGTH

3

1 = Short (ca. 7 mm)
2 = Medium (ca. 8 mm)
3 = Long (ca. 9 mm)

G. WIDTH

3

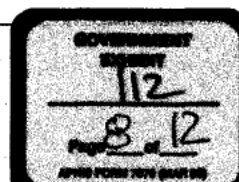
1 = Narrow (ca. 3 mm)
2 = Medium (ca. 3.5 mm)
3 = Wide (ca. 4 mm)

H. PUBESCENCE

2

1 = Not Present
2 = Present

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7

13. SEED:

A. SHAPE

- ☐ 1 = Ovate
☐ 2 = Oval
☐ 3 = Elliptical

B. CHEEK

- ☐ 1 = Rounded
☐ 2 = Angular

C. BRUSH

- ☐ 1 = Short
☐ 2 = Medium
☐ 3 = Long
- ☐ 1 = Not Collared
☐ 2 = Collared

D. CREASE

- ☐ 1 = Width 60% or less of Kernel
☐ 2 = Width 80% or less of Kernel
☐ 3 = Width Nearly as Wide as Kernel

- ☐ 1 = Depth 20% or less of Kernel
☐ 2 = Depth 35% or less of Kernel
☐ 3 = Depth 50% or less of Kernel

E. COLOR

- ☐ 1 = White
☐ 2 = Amber
☐ 3 = Red
☐ 4 = Other (Specify) _____

F. TEXTURE

- ☐ 1 = Hard
☐ 2 = Soft
☐ 3 = Other (Specify) _____

G. PHENOL REACTION (See Instructions)

- ☐ 1 = Ivory
☐ 2 = Fawn
☐ 3 = Light Brown
☐ 4 = Dark Brown
☐ 5 = Black

H. SEED WEIGHT

- ☐ 4 ☐ 1 g/1000 Seed (whole number only)

I. GERM SIZE

- ☐ 1 = Small
☐ 2 = Midsize
☐ 3 = Large

14. DISEASE: PLEASE INDICATE THE SPECIFIC RACE OR STRAIN TESTED

(0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

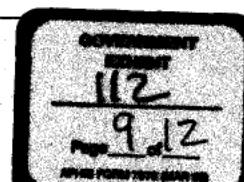
- | | |
|---|---|
| <input type="checkbox"/> 0 Stem Rust (<i>Puccinia graminis</i> f. sp. <i>tritici</i>) | <input type="checkbox"/> 0 Leaf Rust (<i>Puccinia recondita</i> f. sp. <i>tritici</i>) |
| <input type="checkbox"/> 1 Stripe Rust (<i>Puccinia striiformis</i>) Field Races | <input type="checkbox"/> 0 Loose Smut (<i>Ustilago tritici</i>) |
| <input type="checkbox"/> 0 Tan Spot (<i>Pyrenophora tritici-repentis</i>) | <input type="checkbox"/> 0 Flag Smut (<i>Urocystis agropyri</i>) |
| <input type="checkbox"/> 0 Halo Spot (<i>Selenophoma donacis</i>) | <input type="checkbox"/> 0 Common Bunt (<i>Tilletia tritici</i> or <i>T. laevis</i>) |
| <input type="checkbox"/> 0 Septoria nodorum (Glume Blotch) | <input type="checkbox"/> 0 Dwarf Bunt (<i>Tilletia controversa</i>) |
| <input type="checkbox"/> 0 Septoria avenae (Speckled Leaf Disease) | <input type="checkbox"/> 0 Karnal Bunt (<i>Tilletia indica</i>) |
| <input type="checkbox"/> 4 Septoria tritici (Speckled Leaf Blotch) | <input type="checkbox"/> 0 Powdery Mildew (<i>Erysiphe graminis</i> f. sp. <i>tritici</i>) |
| <input type="checkbox"/> 0 Scab (<i>Fusarium</i> spp.) | <input type="checkbox"/> 0 "Snow Molds" |
| <input type="checkbox"/> 0 "Black Point" (Kernel Smudge) | <input type="checkbox"/> 0 Common Root Rot (<i>Fusarium</i> , <i>Cochliobolus</i> and <i>Bipolaris</i> spp.) |
| <input type="checkbox"/> 1 Barley Yellow Dwarf Virus (BYDV) | <input type="checkbox"/> 0 Rhizoctonia Root Rot (<i>Rhizoctonia solani</i>) |
| <input type="checkbox"/> 0 Soilborne Mosaic Virus (SBMV) | <input type="checkbox"/> 0 Black Chaff (<i>Xanthomonas campestris</i> pv. <i>translucens</i>) |
| <input type="checkbox"/> 0 Wheat Yellow (Spindle Streak) Mosaic Virus | <input type="checkbox"/> 0 Bacterial Leaf Blight (<i>Pseudomonas syringae</i> pv. <i>syringae</i>) |
| <input type="checkbox"/> 0 Wheat Streak Mosaic Virus (WSMV) | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |

15. INSECT: (0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

PLEASE SPECIFY BIOTYPE (where needed)

- | | |
|--|--|
| <input type="checkbox"/> 0 Hessian Fly (<i>Mayetiola destructor</i>) | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> 0 Stem Sawfly (<i>Cephus</i> spp.) | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> 0 Cereal Leaf Beetle (<i>Oulema melanopa</i>) | <input type="checkbox"/> Other (Specify) _____ |

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15. INSECT: (continued) (0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

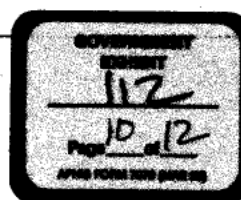
PLEASE SPECIFY BIOTYPE (Where Needed)

2007 00017

- ☒ Russian Aphid (*Diuraphis noxia*)
☒ Greenbug (*Schizaphis graminum*)
☒ Aphids

- ☐ Other (Specify) _____
☐ Other (Specify) _____
☐ Other (Specify) _____

16. ADDITIONAL INFORMATION ON ANY ITEM ABOVE, OR GENERAL COMMENTS:



U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). The information is held confidential until the certificate is issued (7 U.S.C. 2426).

EXHIBIT E
STATEMENT OF THE BASIS OF OWNERSHIP

1. NAME OF APPLICANT(S) WestBred, LLC	2. TEMPORARY DESIGNATION OR EXPERIMENTAL NUMBER DA900-229	3. VARIETY NAME Solano
4. ADDRESS (Street and No., or R.F.D. No., City, State, and ZIP, and Country) 81 Timberline Drive Bozeman, MT 59718	5. TELEPHONE (Include area code) 406-587-1218	6. FAX (Include area code) 406-587-8247
7. PVPO NUMBER		2007 00017

8. Does the applicant own all rights to the variety? Mark an "X" in the appropriate block. If no, please explain.

☒ YES☐ NO

9. Is the applicant (individual or company) a U.S. national or a U.S. based company? If no, give name of country.

☒ YES☐ NO

10. Is the applicant the original owner?

☒ YES☐ NOIf no, please answer one of the following:

a. If the original rights to variety were owned by individual(s), is (are) the original owner(s) a U.S. National(s)?

☐ YES☐ NO

If no, give name of country

b. If the original rights to variety were owned by a company(ies), is (are) the original owner(s) a U.S. based company?

☐ YES☐ NO

If no, give name of country

11. Additional explanation on ownership (Trace ownership from original breeder to current owner. Use the reverse for extra space if needed):

PLEASE NOTE:

Plant variety protection can only be afforded to the owners (not licensees) who meet the following criteria:

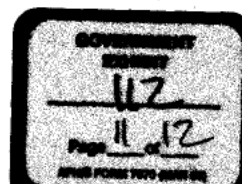
1. If the rights to the variety are owned by the original breeder, that person must be a U.S. national, national of a UPOV member country, or national of a country which affords similar protection to nationals of the U.S. for the same genus and species.
2. If the rights to the variety are owned by the company which employed the original breeder(s), the company must be U.S. based, owned by nationals of a UPOV member country, or owned by nationals of a country which affords similar protection to nationals of the U.S. for the same genus and species.
3. If the applicant is an owner who is not the original owner, both the original owner and the applicant must meet one of the above criteria.

The original breeder/owner may be the individual or company who directed the final breeding. See Section 41(a)(2) of the Plant Variety Protection Act for definitions.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 0.1 hour per response, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 328-W, Whitten Building, 14th and Independence Avenue, SW, Washington, D.C. 20250-9410 or call (202) 720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.



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U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY
PLANT VARIETY PROTECTION OFFICE
BELTSVILLE, MD 20705

EXHIBIT F
DECLARATION REGARDING DEPOSIT

NAME OF OWNER (S) WestBred, LLC	ADDRESS (Street and No. or RD No., City, State, and Zip Code and Country) 81 Timberline Drive Bozeman, MT 59718	TEMPORARY OR EXPERIMENTAL DESIGNATION DA900-229 VARIETY NAME Solano
NAME OF OWNER REPRESENTATIVE (S) (b) (6), (b) (7)(C)	ADDRESS (Street and No. or RD No., City, State, and Zip Code and Country) P.O. Box 6904 Yuma, Az 85366	FOR OFFICIAL USE ONLY PVPO NUMBER 0007 000017

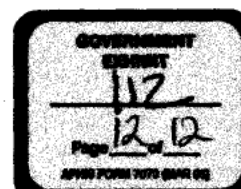
I do hereby declare that during the life of the certificate a viable sample of propagating material of the subject variety will be deposited, and replenished as needed periodically, in a public repository in the United States in accordance with the regulations established by the Plant Variety Protection Office.

(b) (6), (b) (7)(C)

Signature

Oct. 17, 2006

Date



No.

200600273

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

West Bred, LLC

Whereas, THERE HAS BEEN PRESENTED TO THE

Secretary of Agriculture

AN APPLICATION REQUESTING A CERTIFICATE OF PROTECTION FOR AN ALLEGED DISTINCT VARIETY OF SEXUALLY REPRODUCED, OR TUBER PROPAGATED PLANT, THE NAME AND DESCRIPTION OF WHICH ARE CONTAINED IN THE APPLICATION AND EXHIBITS, A COPY OF WHICH IS HEREUNTO ANNEXED AND MADE A PART HEREOF, AND THE VARIOUS REQUIREMENTS OF LAW IN SUCH CASES MADE AND PROVIDED HAVE BEEN COMPLIED WITH, AND THE TITLE THEREOF IS FROM THE RECORDS OF THE PLANT VARIETY PROTECTION OFFICE, IN THE APPLICANT(S) INDICATED IN THE SAID COPY, AND WHEREAS, UPON DUE EXAMINATION MADE, THE SAID APPLICANT(S) IS (ARE) ADJUDGED TO BE ENTITLED TO A CERTIFICATE OF PLANT VARIETY PROTECTION UNDER THE LAW.

NOW, THEREFORE, THIS CERTIFICATE OF PLANT VARIETY PROTECTION IS TO GRANT UNTO THE SAID APPLICANT(S) AND THE SUCCESSORS, HEIRS OR ASSIGNS OF THE SAID APPLICANT(S) FOR THE TERM OF TWENTY YEARS FROM THE DATE OF THIS GRANT, SUBJECT TO THE PAYMENT OF THE REQUIRED FEES AND PERIODIC FURNISHMENT OF VIABLE BASIC SEED OF THE VARIETY IN A PUBLIC REPOSITORY AS PROVIDED BY LAW, THE RIGHT TO EXCLUDE OTHERS FROM SELLING THE VARIETY, OR OFFERING IT FOR SALE, OR REPRODUCING IT, OR PROPAGATING IT, OR EXPORTING IT, OR CONDITIONING IT FOR PROPAGATION, OR STOCKING IT FOR ANY OF THE FOREGOING PURPOSES, OR USING IT IN PRODUCING A HYBRID OR DIFFERENT VARIETY THEREFROM, TO THE EXTENT PROVIDED BY THE PLANT VARIETY PROTECTION ACT. (84 STAT. 1542, AS AMENDED, 7 U.S.C. 2321 ET SEQ.)

WHEAT, COMMON

'WB-528'

In Testimony Whereof, I have hereunto set my hand and caused the seal of the Plant Variety Protection Office to be affixed at the City of Washington, D.C. this ninth day of March, in the year two thousand and seven.

Attest:

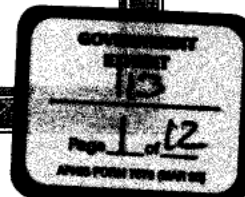
Bilze

Commissioner
Plant Variety Protection Office
Agricultural Marketing Service

Robinson

Secretary

OR120018_BR_003660



WB-528

REPRODUCE LOCALLY. Include form number and date on all reproductions

Form Approved - OMB No. 0581-0055

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY - PLANT VARIETY PROTECTION OFFICE

APPLICATION FOR PLANT VARIETY PROTECTION CERTIFICATE
(Instructions and information collection burden statement on reverse)

The following statements are made in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the Paperwork Reduction Act (PRA) of 1995.

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). Information is held confidential until certificate is issued (7 U.S.C. 2426).

1. NAME OF OWNER WestBred, LLC		2. TEMPORARY DESIGNATION OR EXPERIMENTAL NAME BZ 6W98-528		3. VARIETY NAME WB-528	
4. ADDRESS (Street and No., or R.F.D. No., City, State, and ZIP Code, and Country) 81 Timberline Drive Bozeman, MT 59718 USA		5. TELEPHONE (include area code) (b) (6), (b) (7)(C)		FOR OFFICIAL USE ONLY PVPO NUMBER 200600273 FILING DATE August 22, 2006	
		6. FAX (include area code) 406-586-8247			
7. IF THE OWNER NAMED IS NOT A "PERSON", GIVE FORM OF ORGANIZATION (corporation, partnership, association, etc.) Limited Liability Company		8. IF INCORPORATED, GIVE STATE OF INCORPORATION Arizona		9. DATE OF INCORPORATION August 4, 2003	
10. NAME AND ADDRESS OF OWNER REPRESENTATIVE(S) TO SERVE IN THIS APPLICATION. (First person listed will receive all papers) (b) (6), (b) (7)(C) 81 Timberline Drive Bozeman, MT 59718				FILING AND EXAMINATION FEES: \$ 4382.00 DATE 8/22/2006 CERTIFICATION FEE: \$ 768.00 DATE 02/09/2007	
11. (b) (6), (b) (7)(C)		12. FAX (include area code) 406-586-8247		13. E-MAIL (b) (6), (b) (7)(C) westbred.com	
14. CROP KIND (Common Name) wheat		16. FAMILY NAME (Botanical) Poaceae		18. DOES THE VARIETY CONTAIN ANY TRANSGENES? (OPTIONAL) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF SO, PLEASE GIVE THE ASSIGNED USDA-APHIS REFERENCE NUMBER FOR THE APPROVED PETITION TO DEREGULATE THE GENETICALLY MODIFIED PLANT FOR COMMERCIALIZATION.	
15. GENUS AND SPECIES NAME OF CROP Triticum aestivum		17. IS THE VARIETY A FIRST GENERATION HYBRID? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		20. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE SOLD AS A CLASS OF CERTIFIED SEED? (See Section 83(a) of the Plant Variety Protection Act) <input type="checkbox"/> YES (If "yes", answer items 21 and 22 below) <input checked="" type="checkbox"/> NO (If "no", go to item 23)	
19. CHECK APPROPRIATE BOX FOR EACH ATTACHMENT SUBMITTED (Follow instructions on reverse) a. <input checked="" type="checkbox"/> Exhibit A. Origin and Breeding History of the Variety b. <input checked="" type="checkbox"/> Exhibit B. Statement of Distinctness c. <input checked="" type="checkbox"/> Exhibit C. Objective Description of Variety d. <input type="checkbox"/> Exhibit D. Additional Description of the Variety (Optional) e. <input checked="" type="checkbox"/> Exhibit E. Statement of the Basis of the Owner's Ownership f. <input checked="" type="checkbox"/> Exhibit F. Declaration Regarding Deposit g. <input checked="" type="checkbox"/> Voucher Sample (3,000 viable untreated seeds or, for tuber propagated varieties, verification that tissue culture will be deposited and maintained in an approved public repository) h. <input checked="" type="checkbox"/> Filing and Examination Fee (\$4,382), made payable to "Treasurer of the United States" (Mail to the Plant Variety Protection Office)		21. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE LIMITED AS TO NUMBER OF CLASSES? <input type="checkbox"/> YES <input type="checkbox"/> NO IF YES, WHICH CLASSES? <input type="checkbox"/> FOUNDATION <input type="checkbox"/> REGISTERED <input type="checkbox"/> CERTIFIED		22. DOES THE OWNER SPECIFY THAT SEED OF THIS VARIETY BE LIMITED AS TO NUMBER OF GENERATIONS? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YES, SPECIFY THE NUMBER 1,2,3, etc. FOR EACH CLASS. <input type="checkbox"/> FOUNDATION <input type="checkbox"/> REGISTERED <input type="checkbox"/> CERTIFIED (If additional explanation is necessary, please use the space indicated on the reverse.)	
23. HAS THE VARIETY (INCLUDING ANY HARVESTED MATERIAL) OR A HYBRID PRODUCED FROM THIS VARIETY BEEN SOLD, DISPOSED OF, TRANSFERRED, OR USED IN THE U. S. OR OTHER COUNTRIES? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO Sept. 10, 2005 USA IF YES, YOU MUST PROVIDE THE DATE OF FIRST SALE, DISPOSITION, TRANSFER, OR USE FOR EACH COUNTRY AND THE CIRCUMSTANCES. (Please use space indicated on reverse.)		24. IS THE VARIETY OR ANY COMPONENT OF THE VARIETY PROTECTED BY INTELLECTUAL PROPERTY RIGHT (PLANT BREEDER'S RIGHT OR PATENT)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO IF YES, PLEASE GIVE COUNTRY, DATE OF FILING OR ISSUANCE AND ASSIGNED REFERENCE NUMBER. (Please use space indicated on reverse.)			

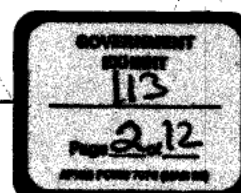
25. The owners declare that a viable sample of basic seed of the variety has been furnished with application and will be replenished upon request in accordance with such regulations as may be applicable, or for a tuber propagated variety a tissue culture will be deposited in a public repository and maintained for the duration of the certificate.

The undersigned owner(s) is(are) the owner of this sexually reproduced or tuber propagated plant variety, and believe(s) that the variety is new, distinct, uniform, and stable as required in Section 42, and is entitled to protection under the provisions of Section 42 of the Plant Variety Protection Act.

Owner(s) is (are) informed that false representation herein can jeopardize protection and result in penalties.

(b) (6), (b) (7)(C) for WestBred, LLC		SIGNATURE OF OWNER (b) (6), (b) (7)(C)	
NAME (Please print or type) (b) (6), (b) (7)(C)		DATE August 21, 2006	
CAPACITY OR TITLE (b) (6), (b) (7)(C)	DATE Aug 21, 2006	CAPACITY OR TITLE (b) (6), (b) (7)(C)	DATE August 21, 2006

(See reverse for instructions and information collection burden statement.)



"WB-528"
Soft White Winter Wheat

200600273

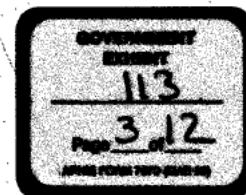
19.a. Exhibit A. Origin and Breeding History

"WB-528" (exp. # BZ 6W98-528) is a soft white winter wheat that originated from the cross of "WestBred 470 x Madsen", made by WestBred, LLC near Bozeman, MT in 1995. The F1 plants were planted near Phoenix, AZ in Nov. 1995, and the F2 seed harvested in May 1996. F2 seed was planted in Oct. 1996 near Burley, ID. Heads were harvested from individual F2 plants and the F3 seed planted as individual rows in the fall of 1998 near Bozeman, MT. The F3 rows were observed for over all agronomic appearance (plant height, lodging resistance and shatter resistance). Agronomically desirable rows were harvested individually, weighed and the grain tested for cookie/cracker/cake quality by measuring test weight, % protein, and SDS sedimentation. Seed from one such row was selected to be advanced and was given the experimental number "BZ 6W98-528". Yield trials, along with quality analysis for soft white wheat, were conducted on the F4 thru F11 generations in WestBred, LLC's Pacific Northwest winter wheat trials. F8-F11 generation seed was tested in Washington, Idaho, and Oregon public trial from 2003 to present. Table 1 provides agronomic performance from several location. WB-528 was tested for quality by the Pacific Northwest Wheat Quality Council in 2004 and found to be acceptable for the soft white wheat market class (Table 2 provides quality data from the USDA/ARS Western Wheat Quality Lab). Individual heads were harvested from the F5 plots and planted as head rows near Bozeman, MT in the fall of 2000. Eight head rows were harvested in September 2001 and planted individually in the fall of 2001 near Bozeman, MT. Uniform plots were harvested in Aug of 2002, bulked, and planted in October, 2003 near Burley, ID. This seed was harvested in August, 2003 and designated Breeder's seed. The Breeder's seed was planted on approximately 40 acres near Quincy, WA in October 2003. Production from this field was harvested in August, 2004 as 'Foundation' and 'Registered' seed. At that time, the name "WB-528" was chosen for the variety. 'Registered' seed was planted in the fall of 2004 and seed from these fields were harvested in August, 2005 as 'Certified' seed. The first unencumbered sale of "WB-528" occurred September 10, 2005.



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

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"WB-528"
Soft White Winter Wheat

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A tall variant that is 1-2 heads taller may occur at a frequency of up to 15 plants per 10,000 plants. Also, a red seed variant may occur at a frequency of up to 12 seed per 10,000 seed. Otherwise, no other variants are known to occur and "WB-528" is a stable and uniform variety in appearance and performance over several generations and growing conditions.

19.b. Exhibit B. Statement of Distinctness

WB-528 is most similar to the variety WestBred 470. However, the glume shoulders of WB-528 are oblique, whereas the glume shoulders of WestBred 470 are square. Also, the milling and baking quality scores of WB-528 are significantly improved over those of WestBred 470 (Table 2)

The above comparison, along with the complete Objective Description (Exhibit C) shows WB-528 to be a novel variety of soft white winter wheat.

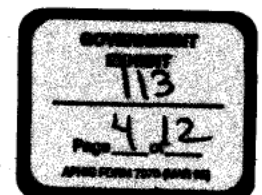
Table 1. Agronomic Characteristics of WB-528 compared to check varieties in Washington State Univ. Trials from 2003 to 2005 (57 locations).

VARIETY NAME	YIELD BU/A	TEST WT	% PROTEIN	PLANT HT	HEAD DATE	LODGE %
WB-528	104.9	61.0	10.5	35.1	6/1	0
CASHUP	103.1	59.7	10.0	33.7	6/5	4
ELTAN	101.5	59.0	10.0	36.8	6/6	38
FINCH	107.5	60.4	10.0	36.5	6/6	9
LAMBERT	104.3	59.1	10.3	37.9	6/1	6
MADSEN	104.0	59.3	10.6	35.3	6/5	0
MOHLER	106.4	59.4	10.2	36.8	6/2	26
STEPHENS	104.6	59.2	10.6	34.6	6/1	9
TUBBS	114.1	58.4	10.0	37.8	6/3	1



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

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"WB-528"
Soft White Winter Wheat

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Table 2. Quality analysis (*t*-scores) of WB-528 compared to currently grown varieties of soft white winter in Washington State University Trials. Analysis performed by USDA/ARS Western Wheat Quality Lab in Pullman, WA. (2003 - 2005 samples)

<u>t values</u>				
<u>VAR</u>	<u>OVERALL</u>	<u>GRAIN</u>	<u>MILLING</u>	<u>BAKING</u>
FINCH	1.47	2.86	-0.69	2.91
CASHUP	1.01	1.08	-1.43	2.95
WB-528	0.38	1.10	-0.83	1.21
ELTAN	0.37	1.62	-0.51	0.83
MOHLER	0.09	2.21	-0.71	0.31
STEPHENS	0.00	0.00	0.00	0.00
LAMBERT	-0.16	-0.20	2.80	-2.52
TUBBS	-1.79	1.99	-1.64	-2.66
MADSEN	-1.96	-2.42	-0.69	-2.89
WB470	-3.60	-1.73	-3.82	-3.79

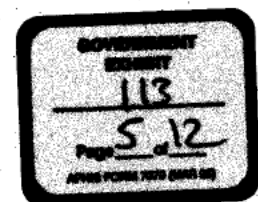
Note: Student's *t* is calculated for each variety compared to the check variety 'Stephens'. Positive values of *t* indicate the test variety has a value greater than the check and negative values indicate that the test variety value is less than the check.

WB-528 was compared with Stephens in 36 location/years of samples. **A difference of 2 is significant.**



WestBred, LLC, 81 Timberline Dr., Bozeman, MT 59718

OR120018_BR_003668



REPRODUCE LOCALLY. Include form number and date on all reproductions.

Form Approved OMB NO 0581-0065

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0065. The time required to complete this information collection is estimated to average 2.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY
PLANT VARIETY PROTECTION OFFICE
BELTSVILLE, MD 20705

Exhibit C

OBJECTIVE DESCRIPTION OF VARIETY
Wheat (*Triticum* spp.)

NAME OF APPLICANT (S) WestBred, LLC	TEMPORARY OR EXPERIMENTAL DESIGNATION BE 6W98-528	VARIETY NAME WB-528
ADDRESS (Street and No. or RD No., City, State, Zip Code and Country) 81 Timberline Dr. Bozeman, MT 59718		PVPO NUMBER 200600273

PLEASE READ ALL INSTRUCTIONS CAREFULLY:

Place the appropriate number that describes the varietal character of this variety in the boxes below. Place a zero in the first box (e.g., 0 9 9 or 0 9) when number is either 99 or less or 9 or less respectively. Data for quantitative plant characters should be based on a minimum of 100 plants. Comparative data should be determined from varieties entered in the same trial. Royal Horticultural Society or any recognized color standard may be used to determine plant colors; designate system used: . Please answer all questions for your variety; lack of response may delay progress of your application.

1. KIND:

- ☐ 1 = Common
☐ 2 = Durum
☐ 3 = Club
☐ 4 = Other (Specify) _____

2. VERNALIZATION:

- ☐ 1 = Spring
☐ 2 = Winter
☐ 3 = Other (Specify) _____

3. COLEOPTILE ANTHOCYANIN:

- ☐ 1 = Absent
☐ 2 = Present

4. JUVENILE PLANT GROWTH:

- ☐ 1 = Prostrate
☐ 2 = Semi-Erect
☐ 3 = Erect

5. PLANT COLOR: (boot stage)

- ☐ 1 = Yellow-Green
☐ 2 = Green
☐ 3 = Blue-Green

6. FLAG LEAF: (boot stage)

- ☐ 1 = Erect
☐ 2 = Recurved
☐ 1 = Not Twisted
☐ 2 = Twisted
☐ 1 = Wax Absent
☐ 2 = Wax Present

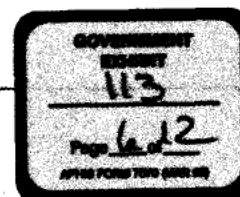
7. EAR EMERGENCE:

- ☐ 1 ☐ 5 ☐ 2 Number of Days (Average)
☐ 0 ☐ 1 Number of Days Earlier Than
Same As
☐ 0 ☐ 3 Number of Days Later Than

* Mohler
* Stephens
* WestBred 470
*Relative to a PVPO-Approved Commercial Variety Grown in the Same Trial

8. ANTER COLOR:

- ☐ 1 = Yellow
☐ 2 = Purple



5

9. PLANT HEIGHT: (from soil to top of head, excluding awns)

089

cm (Average)

04

cm Taller Than

Cash up

Same As

West Bred 470

04

cm Shorter Than

Mohler

200600273

10. STEM:

A. ANTHOCYANIN

1

1 = Absent 2 = Present

B. WAXY BLOOM

2

1 = Absent 2 = Present

C. HAIRINESS (last internode of rachis)

2

1 = Absent 2 = Present

D. INTERNODE

1

1 = Hollow 2 = Semi-Solid 3 = Solid

4

Number of Nodes

E. PEDUNCLE

1

1 = Erect 2 = Recurved 3 = Semi-Erect

27

cm Length

F. AURICLE

1

Anthocyanin: 1 = Absent 2 = Present

1

Hair: 1 = Absent 2 = Present

11. HEAD: (At Maturity)

A. DENSITY

2

1 = Lax
2 = Middense (Laxidense)
3 = Dense

B. SHAPE

2

1 = Tapering
2 = Strap
3 = Clavate
4 = Other (Specify)

C. CURVATURE

2

1 = Erect
2 = Inclined
3 = Recurved

D. AWNEDNESS

4

1 = Awnless
2 = Apically Awnletted
3 = Awnletted
4 = Awned

12. GLUMES: (At Maturity)

A. COLOR

1

1 = White
2 = Tan
3 = Other (Specify)

B. SHOULDER

2

1 = Wanting 2 = Oblique
3 = Rounded 4 = Square
5 = Elevated 6 = Apiculate
7 = Other (Specify)

C. SHOULDER WIDTH

1

1 = Narrow
2 = Medium
3 = Wide

D. BEAK

3

1 = Obtuse
2 = Acute
3 = Acuminate

E. BEAK WIDTH

2

1 = Narrow
2 = Medium
3 = Wide

F. GLUME LENGTH

3

1 = Short (ca. 7 mm)
2 = Medium (ca. 8 mm)
3 = Long (ca. 9 mm)

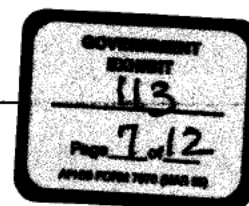
G. WIDTH

3

1 = Narrow (ca. 3 mm)
2 = Medium (ca. 3.5 mm)
3 = Wide (ca. 4 mm)

H. PUBESCENCE

1

1 = Not Present
2 = Present

200600273

13. SEED:

A. SHAPE

- ☒ 1 = Ovate
☐ 2 = Oval
☐ 3 = Elliptical

B. CHEEK

- ☒ 1 = Rounded
☐ 2 = Angular

C. BRUSH

- ☒ 1 = Short
☐ 2 = Medium
☐ 3 = Long
- ☐ 1 = Not Collared
☐ 2 = Collared

D. CREASE

- ☒ 1 = Width 60% or less of Kernel
☐ 2 = Width 80% or less of Kernel
☐ 3 = Width Nearly as Wide as Kernel

- ☒ 1 = Depth 20% or less of Kernel
☐ 2 = Depth 35% or less of Kernel
☐ 3 = Depth 50% or less of Kernel

E. COLOR

- ☒ 1 = White
☐ 2 = Amber
☐ 3 = Red
☐ 4 = Other (Specify) _____

F. TEXTURE

- ☒ 1 = Hard
☐ 2 = Soft
☐ 3 = Other (Specify) _____

G. PHENOL REACTION (See Instructions)

- ☒ 1 = Ivory
☐ 2 = Fawn
☐ 3 = Light Brown
☐ 4 = Dark Brown
☐ 5 = Black

H. SEED WEIGHT

- ☒ 44 g/1000 Seed (whole number only)

I. GERM SIZE

- ☒ 1 = Small
☐ 2 = Midsize
☐ 3 = Large

14. DISEASE: PLEASE INDICATE THE SPECIFIC RACE OR STRAIN TESTED

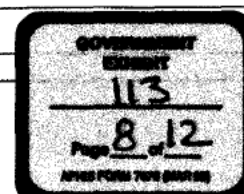
(0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

- | | |
|--|---|
| <input checked="" type="checkbox"/> Stem Rust (<i>Puccinia graminis</i> f. sp. <i>tritici</i>) | <input checked="" type="checkbox"/> Leaf Rust (<i>Puccinia recondita</i> f. sp. <i>tritici</i>) |
| <input checked="" type="checkbox"/> Stripe Rust (<i>Puccinia striiformis</i>) | <input type="checkbox"/> Loose Smut (<i>Ustilago tritici</i>) |
| <input type="checkbox"/> Tan Spot (<i>Pyrenophora tritici-repentis</i>) | <input type="checkbox"/> Flag Smut (<i>Urocystis agropyri</i>) |
| <input type="checkbox"/> Halo Spot (<i>Selenophoma donacis</i>) | <input type="checkbox"/> Common Bunt (<i>Tilletia tritici</i> or <i>T. laevis</i>) |
| <input type="checkbox"/> Septoria nodorum (Glume Blotch) | <input type="checkbox"/> Dwarf Bunt (<i>Tilletia controversa</i>) |
| <input type="checkbox"/> Septoria avenae (Speckled Leaf Disease) | <input type="checkbox"/> Karnal Bunt (<i>Tilletia indica</i>) |
| <input type="checkbox"/> Septoria tritici (Speckled Leaf Blotch) | <input type="checkbox"/> Powdery Mildew (<i>Erysiphe graminis</i> f. sp. <i>tritici</i>) |
| <input type="checkbox"/> Scab (<i>Fusarium</i> spp.) | <input checked="" type="checkbox"/> "Snow Molds" |
| <input checked="" type="checkbox"/> "Black Point" (Kernel Smudge) | <input type="checkbox"/> Common Root Rot (<i>Fusarium</i> , <i>Cochliobolus</i> and <i>Bipolaris</i> spp.) |
| <input type="checkbox"/> Barley Yellow Dwarf Virus (BYDV) | <input type="checkbox"/> Rhizoctonia Root Rot (<i>Rhizoctonia solani</i>) |
| <input type="checkbox"/> Soilborne Mosaic Virus (SBMV) | <input type="checkbox"/> Black Chaff (<i>Xanthomonas campestris</i> pv. <i>translucens</i>) |
| <input type="checkbox"/> Wheat Yellow (Spindle Streak) Mosaic Virus | <input type="checkbox"/> Bacterial Leaf Blight (<i>Pseudomonas syringae</i> pv. <i>syringae</i>) |
| <input type="checkbox"/> Wheat Streak Mosaic Virus (WSMV) | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Other (Specify) _____ | <input type="checkbox"/> Other (Specify) _____ |

15. INSECT: (0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

PLEASE SPECIFY BIOTYPE (where needed)

- | | |
|---|--|
| <input type="checkbox"/> Hessian Fly (<i>Mayetiola destructor</i>) | <input type="checkbox"/> Other (Specify) _____ |
| <input type="checkbox"/> Stem Sawfly (<i>Cephus</i> spp.) | <input type="checkbox"/> Other (Specify) _____ |
| <input checked="" type="checkbox"/> Cereal Leaf Beetle (<i>Oulema melanopa</i>) | <input type="checkbox"/> Other (Specify) _____ |



15. INSECT: (continued) (0 = Not Tested 1 = Susceptible 2 = Resistant 3 = Intermediate 4 = Tolerant)

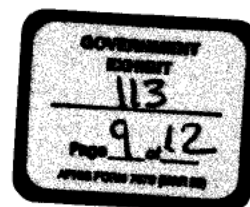
PLEASE SPECIFY BIOTYPE (Where Needed)

200600273

- ☐ Russian Aphid (*Diuraphis noxia*)
☐ Greenbug (*Schizaphis graminum*)
☐ Aphids

- ☐ Other (Specify) _____
☐ Other (Specify) _____
☐ Other (Specify) _____

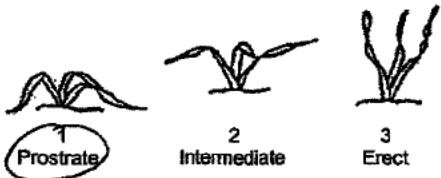
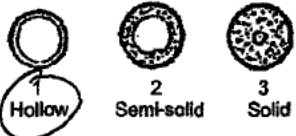


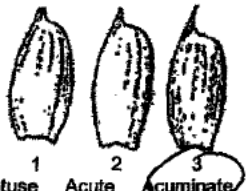


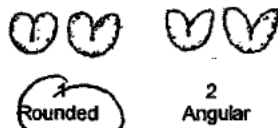



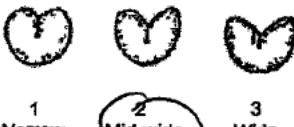

16. ADDITIONAL INFORMATION ON ANY ITEM ABOVE, OR GENERAL COMMENTS:

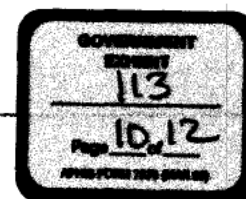


WHEAT DESCRIPTOR ILLUSTRATIONS

200600273

Section Numbers Correspond to the Numbers of the Sections on the Form

<p>4. EARLY PLANT GROWTH HABIT:</p>  <p>1 Prostrate 2 Intermediate 3 Erect</p>	<p>10. (D.) STEM INTERNODE X-SECTION:</p>  <p>1 Hollow 2 Semi-solid 3 Solid</p>	<p>11. (B.) SPIKE SHAPE:</p>  <p>1 Tapering 2 Oblong 3 Clavate 4 Elliptical</p>	
<p>11. (D.) AWNEDNESS:</p>  <p>1 Awnless 2 Apically Awnleted 3 Awnleted 4 Awned</p>	<p>12. (D.) BEAK SHAPE:</p>  <p>1 Obtuse 2 Acute 3 Acuminate</p>	<p>12. (C.) SHOULDER SHAPE:</p>  <p>1 Wanting 2 Oblique 3 Rounded 4 Square 5 Elevated 6 Apiculate</p>	
<p>13. (A.) SEED SHAPE:</p>  <p>1 Ovate 2 Oval 3 Elliptical</p>	<p>13. (B.) CHEEK SHAPE:</p>  <p>1 Rounded 2 Angular</p>	<p>13. (C.) BRUSH SIZE</p>  <p>1 Small 2 Midsized 3 Large 4 Collared</p>	<p>13. (C.) BRUSH HAIR LENGTH:</p>  <p>1 Short 2 Medium 3 Long</p>
<p>13. (I.) GERM (EMBRYO) SIZE:</p>  <p>1 Small 2 Midsized 3 Large</p>	<p>13. (D.) SEED CREASE WIDTH:</p>  <p>1 Narrow 2 Mid-wide 3 Wide</p>	<p>13. (D.) SEED CREASE DEPTH:</p>  <p>1 Shallow 2 Mid-Deep 3 Deep</p>	



REPRODUCE LOCALLY. Include form number and edition date on all reproductions.

FORM APPROVED - OMB No. 0581-0055

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

Application is required in order to determine if a plant variety protection certificate is to be issued (7 U.S.C. 2421). The information is held confidential until the certificate is issued (7 U.S.C. 2426).

EXHIBIT E
STATEMENT OF THE BASIS OF OWNERSHIP

1. NAME OF APPLICANT(S) WestBred, LLC	2. TEMPORARY DESIGNATION OR EXPERIMENTAL NUMBER BZ 6W98-528	3. VARIETY NAME WB-528
4. ADDRESS (Street and No., or R.F.D. No., City, State, and ZIP, and Country) 81 Timberline Drive Bozeman, MT 59718	5. TELEPHONE (Include area code) (b) (6), (b) (7)(C)	6. FAX (Include area code) (406) 586-8247
7. PVPO NUMBER 200600273		

8. Does the applicant own all rights to the variety? Mark an "X" in the appropriate block. If no, please explain. ☒ YES ☐ NO9. Is the applicant (individual or company) a U.S. national or a U.S. based company? If no, give name of country. ☒ YES ☐ NO10. Is the applicant the original owner? ☒ YES ☐ NO If no, please answer one of the following:

a. If the original rights to variety were owned by individual(s), is (are) the original owner(s) a U.S. National(s)?

☐ YES ☐ NO If no, give name of country

b. If the original rights to variety were owned by a company(ies), is (are) the original owner(s) a U.S. based company?

☐ YES ☐ NO If no, give name of country

11. Additional explanation on ownership (Trace ownership from original breeder to current owner. Use the reverse for extra space if needed):

PLEASE NOTE:

Plant variety protection can only be afforded to the owners (not licensees) who meet the following criteria:

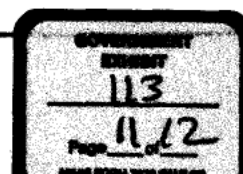
1. If the rights to the variety are owned by the original breeder, that person must be a U.S. national, national of a UPOV member country, or national of a country which affords similar protection to nationals of the U.S. for the same genus and species.
2. If the rights to the variety are owned by the company which employed the original breeder(s), the company must be U.S. based, owned by nationals of a UPOV member country, or owned by nationals of a country which affords similar protection to nationals of the U.S. for the same genus and species.
3. If the applicant is an owner who is not the original owner, both the original owner and the applicant must meet one of the above criteria.

The original breeder/owner may be the individual or company who directed the final breeding. See Section 41(a)(2) of the Plant Variety Protection Act for definitions.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 0.1 hour per response, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW, Washington, D.C. 20250-9410 or call (202) 720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.



REPRODUCE LOCALLY. Include form number and date on all reproductions.

Form Approved OMB NO 0581-0055

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0055. The time required to complete this information collection is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at 202-720-2600 (voice and TDD).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 14th and Independence Avenue, SW, Washington, DC 20250-9410 or call 202-720-5864 (voice and TDD). USDA is an equal opportunity provider and employer.

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
SCIENCE AND TECHNOLOGY
PLANT VARIETY PROTECTION OFFICE
BELTSVILLE, MD 20705

EXHIBIT F
DECLARATION REGARDING DEPOSIT

NAME OF OWNER (S) WestBred, LLC	ADDRESS (Street and No. or RD No., City, State, and Zip Code and Country) 81 Timberline Drive Bozeman, MT 59718	TEMPORARY OR EXPERIMENTAL DESIGNATION BZ 6W98-528
NAME OF OWNER REPRESENTATIVE (S) (b) (6), (b) (7)(C)	ADDRESS (Street and No. or RD No., City, State, and Zip Code and Country) 81 Timberline Drive Bozeman, MT 59718	VARIETY NAME WB-528 PVPO NUMBER 200600273

I do hereby declare that during the life of the certificate a viable sample of propagating material of the subject variety will be deposited, and replenished as needed periodically, in a public repository in the United States in accordance with the regulations established by the Plant Variety Protection Office.

(b) (6), (b) (7)(C)

Signature

for WestBred, LLC

Date

Aug 21, 2006



AVOCET

Pedigree Thatcher – Agropyron elongatum
translocation/3*

Pinnacle/WW-15/3/Egret

Registration data 1979, by NSW (New South Wales)

Department of Agriculture

Abbreviation – Aoc

Maturity Early

Pathogen resistance Flag smut, stem rust (Sr5, Sr26)

Leaf rust (LrEg), stripe rust

Quality type Biscuit wheat

Growth sites South NSW, Vic

Plant characters

1 3-6 leaf stage

- 1.1 Auricle - hairy
- 1.2 Habit - intermediate
- 1.3 Leaf length - long
- 1.4 Leaf width - medium to wide
- 1.5 Leaf pubescence - medium
Light to mid green leaves

2 6-8 leaf stage

- 2.1 Auricle - hairy
- 2.2 Habit - intermediate
- 2.3 Leaf length - long
- 2.4 Leaf width - narrow
- 2.5 Leaf pubescence - medium

3 Flowering

- 3.1 Top auricle height - tall
- 3.2 Flag leaf length - long
- 3.3 Flag leaf width - medium

4 Maturity

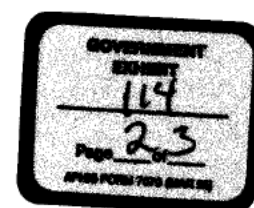
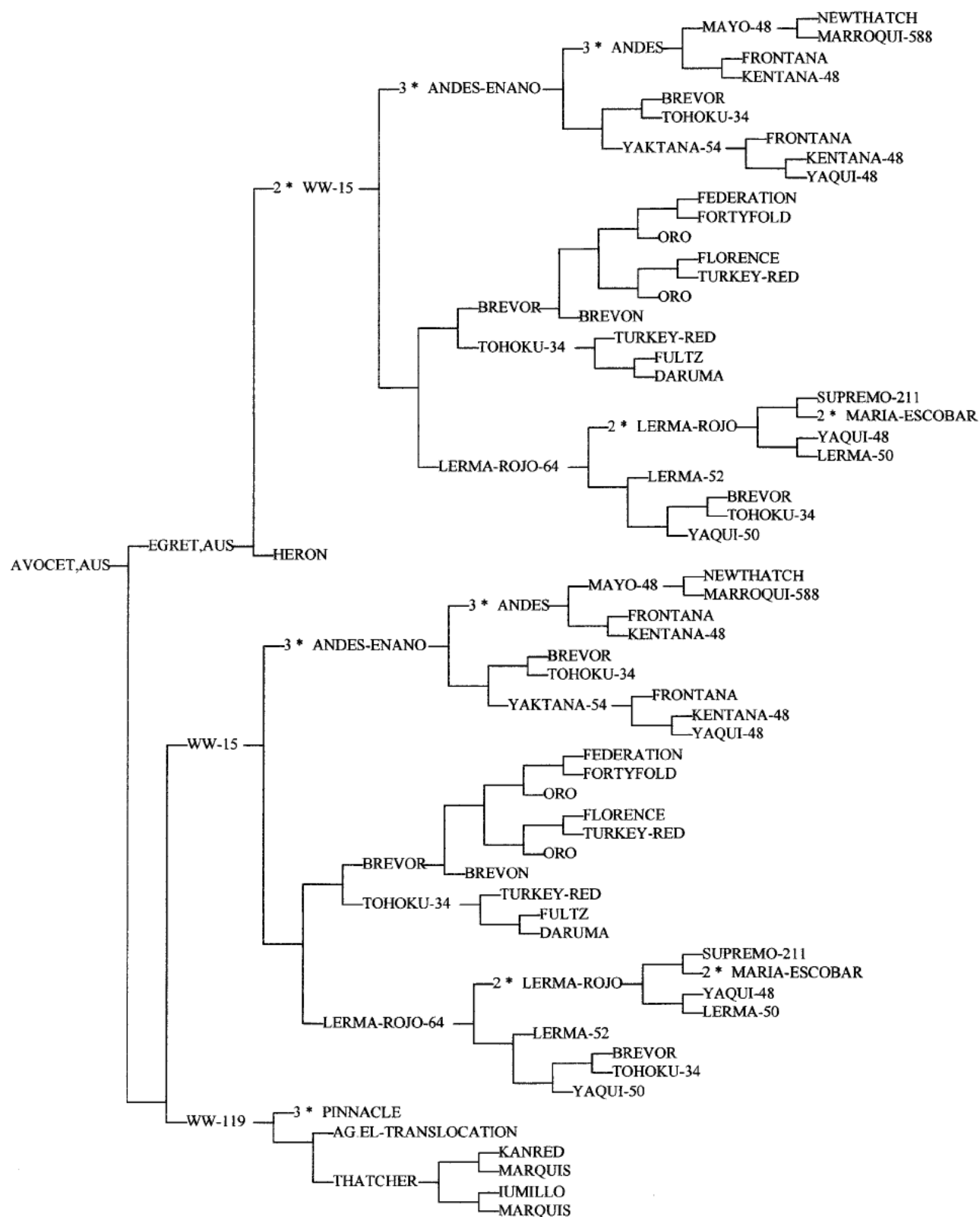
- 4.1 Plant height - short
- 4.2 Straw strength - medium to strong
Thick straw

5 Head Characters

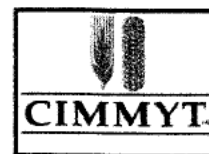
- 5.1 Glume color - white
- 5.2 Awns - fully awned
- 5.3 Head cross section - flattened
- 5.4 Head, side view - oblong to medium
- 5.5 Head density - medium to lax
- 5.6 Head length - long
- 5.7 Glume beak length - long
- 5.8 Glume shoulder - level to elevated
- 5.9 Glume length - long
- 5.10 Glume width - narrow to medium

6 Grain characters

- 6.1 Grain hardness - soft
- 6.2 Grain length - long
- 6.3 Grain width - medium
- 6.4 Brush length - medium
- 6.5 Brush-end profile - pointed
- 6.6 Germ width - wide
- 6.7 Height/width ratio - low to square
- 6.8 Color - medium
- 6.9 Grain texture - opaque
Large grain



OR120018_BR_003686

[Home](#)[Dictionaries](#)[About GRIS](#)

GRIS

Genetic Resources Information System for Wheat and Triticale

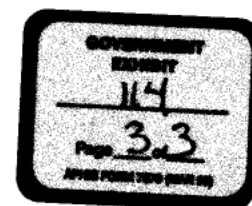
Last
update :
2014-01-
02

[Accession List](#)[AVOCET,AUS Pedigree](#)

AVOCET,AUS

[Page 1](#)[Page 2](#)

Name	AVOCET,AUS
Accession number	K-63214; PI-464644; AUS-20601; AFRC-6896
Pedigree	WW-119/WW-15//EGRET,AUS[113][760][851];
Species	TR.AE
Bot. variety	graecum[113][3854]
Habit	S
Locality	AUS:New-South-Wales
Gene	Rht1[162][1302]; Sr5,Sr26[117][77][1484][2636]; Sr26[776][3599]; Sr5,Sr26,Sr42[3733]; Lr13[77][200][311][1484][2636]; Nor-B1c,Nor-B2c[758]; YrA/yrA[1484][3599]; Glu-A1c,Glu-B1b,Glu-D1d[1335]; Glu-A3e,Glu-B3b,Glu-D3c[1335][3535]; Gli-B1b[1361];
Synonym	WW-179[113][760][1350]; WAGGA-WAGGA-179[113];
Status	CV
Year	1979
Note	AVOCET-A:c,b,a; AVOCET-B:c,b,d; AVOCET-C:a,e,a[3212];



OR120018_BR_003688

UNITED STATE DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
WASHINGTON, D.C.

AND

WASHINGTON AGRICULTURAL RESEARCH CENTER
WASHINGTON STATE UNIVERSITY
PULLMAN, WASHINGTON

AND

IDAHO AGRICULTURAL EXPERIMENT STATION
UNIVERSITY OF IDAHO
MOSCOW, IDAHO

AND

OREGON AGRICULTURAL EXPERIMENT STATION
OREGON STATE UNIVERSITY
CORVALLIS, OREGON

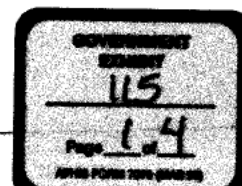
RELEASE OF MADSEN (PI 511673) A SOFT WHITE COMMON WINTER WHEAT CULTIVAR

The Agricultural Research Service, U.S. Department of Agriculture, the Washington Agricultural Research Center, Idaho Agricultural Experiment Station and the Oregon Agricultural Experiment Station announce the joint release of 'Madsen', a soft-white common winter wheat (Triticum aestivum L.) cultivar. Madsen was developed by the cooperative Federal - State research program at Pullman, Washington, and named in honor of former Dean of the College of Agriculture of Washington State University, the late Louis L. Madsen.

R. E. Allan selected Madsen as a F₂ derived F₃ line in 1980 from the cross VPML/Moisson951//2*Hill 81. Madsen is a one-gene semidwarf (Rht₁) that heads mid-early with fully awned spikes. It is heterogeneous for white and light tan glumes yet has white straw. Its kernels are white, large, soft, ovate with a medium germ.

Madsen has resistance to strawbreaker foot rot. It has expressed field resistance to the currently prevalent northwestern USA races of stripe, leaf and stem rust. Madsen is moderately susceptible to flag smut, cephalosporium stripe, and powdery mildew. It has resistance to a few races of the common bunt fungus but it is susceptible to dwarf bunt.

Madsen is the first USA soft white common winter wheat with notable resistance to strawbreaker foot rot. In 1981 to 1986 foot rot inoculated yield trials, Madsen had a mean yield loss of 7%; compared to 17 to 33% losses for Stephens, Daws, and Nugaines. The 6 year mean yield of Madsen in the foot rot inoculated yield tests was 7670 kg/ha vs 4580 to 5180 kg/ha for Nugaines, Daws and Stephens. Madsen has generally had moderately high yields when foot rot is not a factor. In 75 Washington State trials, the mean



yields of Madsen, Stephens, Nugaines, Daws and Lewjain have been 4840, 4350, 4470, 4790 and 5000 kg/ha, respectively. In regional trials outside Washington State, Madsen has varied in its yield potential. In 24 such trials Madsen, Nugaines, Stephens and Dusty produced mean yields of 5590, 4850, 5520, 5650 kg/ha, respectively.

The grain volume weight of Madsen averages about 1.9 kg/hl less than Nugaines and 1.3 kg/hl more than Stephens. It has an average plant height of 80 cm vs. 79, 75 and 77 for Daws, Stephens and Lewjain, respectively. Straw strength of Madsen exceeds Lewjain and Dusty but is less than Stephens. Madsen has a tendency to shatter. It has seedling emergence properties that are superior to Daws but less than Stephens. Madsen has not suffered appreciable winter injury during its testing period in Washington State trials. A crown freeze test indicated Madsen was similar to Stephens for coldhardiness. Occasionally Madsen exhibits a few open florets and partial male sterility.

Tests by the USDA-ARS Western Wheat Quality Laboratory have rated Madsen as promising to particularly promising for overall quality traits. It has also been rated promising in the Pacific Northwest Collaborator Tests. Madsen usually rates above Nugaines and Stephens for cookie diameter, sponge cake score and cake volume. It equals and exceeds the noodle scores of Nugaines and Stephens, respectively.

Madsen may be grown on the northwestern USA where strawbreaker foot rot and the rusts are production limitations. It may perform less well in areas where problems with cold injury and stand establishment occur.

Breeder and foundation seed will be maintained by the Washington State Crop Improvement Association under supervision of the Agronomy and Soils Department, Washington Agricultural Research Center. ARS/USDA has no seed for distribution. The proposed release date for publicity shall be on the date of final signature of the release notice.

T. B. Kinney

Administrator for Agricultural Research Service
United States Department of Agriculture
Washington, D. C.

(b)(6), (b)(7)(c)

[Redacted]

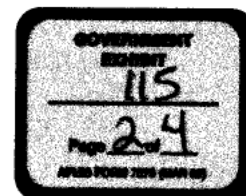
Director
Washington Agricultural Research Center
Washington State University
Pullman, Washington

JAN 7 1988

Date

12-16-87

Date



(b)(6), (b)(7)(c)

Director
Idaho Agricultural Experiment
University of Idaho
Moscow, Idaho

12-19-87

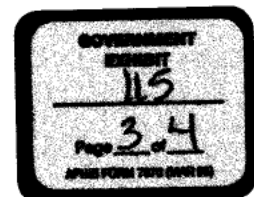
Date

(b)(6), (b)(7)(c)

for Director
Oregon Agricultural Experiment Station
Oregon State University
Corvallis, Oregon

12-29-87

Date





WASHINGTON STATE CROP IMPROVEMENT ASSOCIATION

509-248-3240, Fax 509-452-0616

114 North 5th Avenue
Yakima, Washington 98902-2642

August 24, 1994

TO: Oregon Seed Certification
Attention: (b)(6), (b)(7)
(b)(6), (b)(7)(C)

FROM: (b)(6), (b)(7)(c)

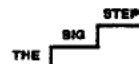
RE: Madsen Winter Wheat
Rod Winter wheat

Results of sodium hydroxide exams of Madsen and Rod winter wheat seed lots indicate varying amounts of red wheat. Until further notice, WSCIA will certify registered or certified class seed lots of Madsen and Rod winter wheat having up to a maximum of 20 seeds/lb of red wheat.

/ggg



PLANT CERTIFIED SEED



TO INCREASED PRODUCTION

OR120018_BR_003696



MAR 19 1992 RECEIVED

COLLEGE OF AGRICULTURAL RESEARCH CENTER
WASHINGTON STATE UNIVERSITY
PULLMAN, WASHINGTON

AND

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
WASHINGTON, D. C.

AND

IDAHO AGRICULTURAL EXPERIMENT STATION
UNIVERSITY OF IDAHO
MOSCOW, IDAHO

AND

OREGON AGRICULTURAL EXPERIMENT STATION
OREGON STATE UNIVERSITY
CORVALLIS, OREGON

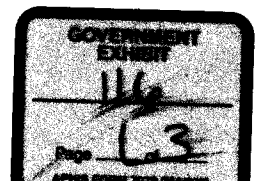
NOTICE OF RELEASE OF 'ROD' (PI558510) A SOFT WHITE WINTER
WHEAT FOR PRODUCTION IN THE PACIFIC NORTHWEST.

The College Agricultural Research Center, Washington State University, and the Agricultural Research Service, United States Department of Agriculture the Idaho Agricultural Experiment Station, University of Idaho, and the Oregon Agricultural Experiment Station, Oregon State University, announce the release of a soft white winter wheat named 'Rod' (PI558510). This cultivar was developed in the cooperative Federal-State research program at Pullman, Washington. and named in honor of the former Chairman of the Crops and Soil Sciences department, at Washington State University, Rod Bertramson.

Rod (WA007662, VH086206) was selected in the f4 by C.J. Peterson Jr. from the cross Luke/Daws/ Hill81. It is a white chaffed semidwarf soft white winter wheat.

Rod is a high yielding winter wheat that is resistant to the local races of stripe rust, and common bunt. Rod is susceptible to leaf rust, stem rust, snow mold, strawbreaker foot rot, Cephalosporium stripe, and dwarf bunt. When the grain production was averaged over 38 site/years (table 1) Rod produced 80 bushels/acre. This was 2.5, 2.6, and 8 percent better than Kmor, Madsen, and Stephens, respectively. Bushel weight of Rod averaged 59.0 over 28 site/years of testing. Kmor, Stephens, and Madsen had a bushel weight of 58.6, 58.2, and 59.4 respectively over these same tests. Rod is approximately 2 inches shorter than Madsen and it matures about 2 days later than Madsen. Tests conducted by the USDA-ARS Western Wheat Quality Laboratory have

OR120018_BR_003698



found that Rod has satisfactory milling and baking quality. Rod equals Nugaines, Daws, and Stephens in milling score, and baking quality.

Publicity for Rod will be handled through the release notice and informal notification in the Wheat Newsletter. Rod will be submitted for registration by the Crop Science Society of America. Breeder and Foundation seed will be maintained by the Washington State Crop Improvement Association under the supervision of the Agronomy and Soils Department, College of Agriculture Research Center, Washington State University, Pullman, Washington 99164.

The proposed release date is June 1, 1992. Each agency involved in the agreement may make news releases as it considers appropriate after the release date.

(b)(6), (b)(7)(c)

Director
College of Agricultural Research Center
Washington State University
Pullman, Washington

W. L. Thurman

Administrator
Agricultural Research Service
U.S. Department of Agriculture

(b)(6), (b)(7)(c)

Director
Idaho Agricultural Experiment Station
University of Idaho
Moscow, Idaho

(b)(6), (b)(7)(c)

Director
Oregon Agricultural Experiment Station
Oregon State University
Corvallis, Oregon

1-7-92

Date

JAN 31 1992

Date

1-7-92

Date

1-7-92

Date





WASHINGTON STATE CROP IMPROVEMENT ASSOCIATION, INC.

509-248-3240, FAX 509-452-0616

114 North 5th Avenue
Yakima, Washington 98902-2642

August 20, 1993

TO: Oregon Seed Certification
Attention: (b)(6), (b)(7)

FROM: (b)(6), (b)(7)(c)

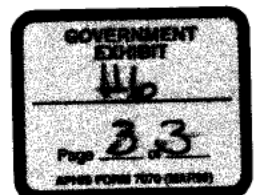
RE: Rod Winter Wheat

Please note the attached description for Rod winter wheat. WSCIA will certify registered or certified class seed lots of Rod winter wheat having up to a maximum of 20 seeds/lb. of red wheat.

/ggg



PLANT CERTIFIED SEED BIG STEP TO INCREASED PRODUCTION
OR120018 BR_003702



United States Department of Agriculture
Agricultural Research Service
Washington, D.C.

and

Washington Agricultural Research Center
Washington State University
Pullman, Washington

and

Oregon Agricultural Experiment Station
Oregon State University
Corvallis, Oregon

and

Idaho Agricultural Experiment Station
University of Idaho
Moscow, Idaho

RELEASE OF CODA (PI594372) A SOFT WHITE CLUB
WINTER WHEAT VARIETY

The Agricultural Research Service, U.S. Department of Agriculture, the Washington Agricultural Research Center, Idaho Agricultural Experiment Station, and the Oregon Agricultural Experiment Station announce the joint release of 'Coda' a soft-white winter (SWW) club wheat variety. Coda was developed by R.E. Allan, Collaborating Geneticist, USDA-ARS, in cooperation with the Federal-State research programs at Pullman, Washington. Coda is being released to provide Pacific Northwest growers the option of producing SWW club variety that has resistance to strawbreaker foot rot, high yield potential, and satisfactory milling and baking quality.

Coda (WA7752, ARS9131) was derived from a $F_2:F_6$ line of the cross Tres//Madsen/Tres in 1991. This line was heterogeneous for resistance to strawbreaker foot rot. Four $F_6:F_{10}$ lines homozygous for the *Pch1* gene for resistance to foot rot were blended equally to constitute breeder seed. Coda is a one-gene, semidwarf with elliptical to dense awned, white glumed spikes with kernels that are white, short, soft,

ovate, germ small; crease midwide; cheeks rounded; brush midshort to short. Grain samples of Coda consistently grade as white club by Federal Grain Inspectors.

Coda has race specific resistance to several biotypes of the stripe rust fungus. It is heterogeneous for adult plant nonspecific resistance. Coda rates intermediate for field resistance to powdery mildew, leaf rust and for tolerance to physiologic leaf spot. Coda has medium tolerance to *Cephalosporium* stripe exceeding other currently grown club wheat varieties. It is moderately susceptible to common bunt and *Septoria* leaf blotch but susceptible to dwarf bunt and stem rust.

The grain yields of Coda have usually equaled or exceeded other semidwarf club wheat varieties. In 55 tests in Washington, Coda exceeded the yield of Hiller (2 percent), Hyak (3 percent), Rely (11 percent), Rohde (11 percent), and Tres (15 percent). In tests where strawbreaker reduced yields Coda exceeded the yields of Hiller, Rohde, Rely, and Tres by 23 to 34 percent. In 34 regional tests at 10 sites in Idaho, Montana, Oregon and Washington Coda has equaled or exceeded the yield of Tres, Moro and Stephens at all sites and equaled or exceeded the yields of Hiller at 8 sites.

Coda has a mean grain volume weight slightly less than Rohde and 10 to 30 grams per liter heavier than Tres, Rely and Moro. It is similar to Tres for plant height having straw strength and lodging vulnerability similar to Rely. Coda is more prone to lodging than Hyak and Rohde. Field tests suggest coldhardiness of Coda is similar to Rely. In artificial freeze tests, it is similar to Rohde but hardier than Stephens. Emergence of Coda is similar to most other semidwarf club varieties; it is superior to Hiller.

Extensive quality tests by the USDA-ARS Western Wheat Quality Lab indicated that overall milling performance of Coda is similar or better than existing club varieties. Flour viscosity, mixograph water absorption, cookie diameter and sponge cake quality are all better than or equal to one or more of the existing club wheat varieties. Coda has the optimal high molecular weight glutenin subunits desired in club wheat at each of the three Glu-1 loci.

Coda is adapted to areas of northwestern USA where semidwarf club wheat varieties can be grown.

Breeder and foundation seed of Coda will be maintained by the Washington State Crop Improvement Association under supervision of the Department of Crop and Soil Sciences, Washington State Agricultural Research Center. The proposed release date for publicity shall be on the date of final signature of the release notice. Genetic

material of this release will be deposited in the National Plant Germplasm System where it will be available for research purposes, including development and commercialization of new varieties.

(b)(6), (b)(7)(c)

Director
Washington Agricultural Research Center
Washington State University
Pullman, Washington

11-20-97

Date

(b)(6), (b)(7)(c)

Director
Oregon Agricultural Experiment Station
Oregon State University
Corvallis, Oregon

12-16-97

Date

(b)(6), (b)(7)(c)

Director
Idaho Agricultural Experiment Station
University of Idaho
Moscow, Idaho

11/25/97

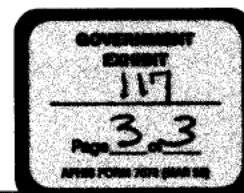
Date

Edward B. Knisling

Administrator for Agricultural Research Service
United States Department of Agriculture
Washington, D.C.

JAN 1 1998

Date



DECLARATION OF (b) (6), (b) (7)(C)

I declare that my name is (b) (6), (b) (7)(C), I am over the age of eighteen and I am fully competent to make this declaration. I know each of the facts set forth herein based on personal firsthand knowledge:

I am an Investigator for the Investigative and Enforcement Services (IES), Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA). My Official Duty Station is located in Oregon. I have held this position since 1998.

As an Investigator for IES, my primary duty is to investigate potential violations of federal laws. As part of this process I collect evidence, take affidavits and document my findings in a report of investigation.

In July 2013, I reviewed several of Monsanto's notifications and discovered many discrepancies in the final reports such as the disposition of harvested material; the lack of monitoring for volunteers, and the method of devitalization or final disposition of plot area

The following is a list of notifications I reviewed with the issues I found during my review:

Notification No. 00-195-04n

Wheat Field Trial Report dated 10/11/01 by Monsanto Company

Site #1 (b) (4) AZ Harvest Date: 05/12/01 Destruct Date: 07/03/01

Disposition of Harvested Material: 69 pounds of the harvested material was shipped to Western Plant Breeders, Bozeman, MT

140 pounds of Roundup Ready® Brooks F4 head rows, 80 pounds Roundup Ready® Express F4 head rows and 9 pounds F3 populations were stored (b) (4) AZ.

Concerns: Where is this material? What happened to the Roundup Ready® head rows that were stored in (b) (4), AZ?

Wheat Field Trial Report dated 10/11/01 by Monsanto Company

Site #2 (b) (4), HI Harvest Date: 04/16/01 Destruct Date: 05/31/01

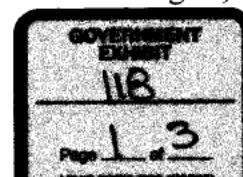
Disposition of Harvested Material: The harvested material was mailed to (b) (4) MO

Monitoring for Volunteer Plants: The plot area was monitored for volunteers April 4, June 8 and July 25, 2001. No volunteers were observed. The plot was watered with an overhead sprinkler and greater than 400 volunteers were seen on August 29, 2001. The area was disked to destroy the volunteers.

Method of Devitalization or Final Disposition of Plot Area after Harvesting: Plot was destroyed by burning on May 31, 2001.

Concerns: When was this seed sent to Monsanto and where is it now? The plot was monitored for volunteers in April, June and July with no volunteers. It was watered and in August they found 400 volunteers. The area was disked to destroy the volunteers? The report does not show that the area was monitored for volunteers after August, 2001? The

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report shows that the plot was destroyed by burning on May 31, 2001, but over 400 volunteers were seen in August, three months later?

Wheat Field Trial Report dated AMENDED 11/21/02 by Monsanto Company

Site #1 (b) (4) AZ Harvest Date: 05/12/01 Destruct Date: 07/03/01

Disposition of Harvested Material: 69 pounds of the harvested material was shipped to (b) (4), MT

140 pounds of Roundup Ready® Brooks F4 head rows, 80 pounds Roundup Ready® Express F4 head rows and 9 pounds F3 populations were stored (b) (4), AZ.

AMENDED: Part of the harvest seed was shipped to (b) (4), MT. The remainder was stored.

Concerns: Where is this material? What happened to the Roundup Ready® head rows that were stores in (b) (4), AZ? Where is the remainder stored? How much seed was stored?

Wheat Field Trial Report dated AMENDED 11/21/02 by Monsanto Company

Site #2 (b) (4), HI Harvest Date: 04/16/01 Destruct Date: 05/31/01

Disposition of Harvested Material: The harvested material was mailed to (b) (4), MO

Monitoring for Volunteer Plants: The plot area was monitored for volunteers April 4, June 8 and July 25, 2001. No volunteers were observed. The plot was watered with an overhead sprinkler and greater than 400 volunteers were seen on August 29, 2001. The area was disked to destroy the volunteers. AMENDED: The plot was monitored for volunteers. Volunteers were destroyed by disking after irrigating to promote volunteer growth.

Method of Devitalization or Final Disposition of Plot Area after Harvesting: Plot was destroyed by burning on May 31, 2001.

Concerns: When was this seed sent to Monsanto and where is it now? The plot was monitored for volunteers in April, June and July with no volunteers. It was watered and in August they found 400 volunteers. The area was disked to destroy the volunteers? The report does not show that the area was monitored for volunteers after August, 2001? The report shows that the plot was destroyed by burning on May 31, 2001, but over 400 volunteers were seen in August, three months later?

Notification No. 99-259-04n

1999 Wheat Field Test Report dated 04/16/01 by Monsanto Company

Site #1 (b) (4) AZ Harvest Date: 05/02/00 Destruct Date: None

Disposition of the seed: Harvested seed was shipped to Montana.

There is no report on the monitoring of the field for volunteers.

Concerns: Where is this material and what happened to it? Did anyone monitor this field for volunteers? What was the final disposition of the field?

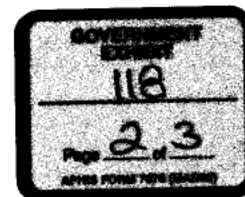
1999 Wheat Field Test Report dated 10/04/00 by Monsanto Company

Site #2 (b) (4), HI Harvest Date: 05/02/00

Disposition of Harvested Material: Harvested seed was shipped to Montana.

Monitoring for Volunteer Plants: Nothing mentioned in report

Method of Devitalization or Final Disposition of Plot Area after Harvesting: Nothing mentioned in report.



Concerns: Where is this seed and what happened to it? Did anyone monitor this field for volunteers? What was the final disposition of the field?

Notification No. 00-005-01n

2000 Wheat Field Trial Report dated 06/08/01 by Monsanto Company

Site located in (b) (4), CO Harvest Date: 08/02/00 Destruct Date: None

Disposition of the harvested material: Some of the harvested seed was shipped to (b) (4), KS.

The remainder was placed in storage at (b) (4), CO.

There is no report on the monitoring of the field for volunteers.

Concerns: Where is this material and what happened to it? Did anyone monitor this field for volunteers? What was the final disposition of the field?

1999 Wheat Field Test Report dated 10/04/00 by Monsanto Company

Site #2 (b) (4), HI Harvest Date: 05/02/00

Disposition of Harvested Material: Harvested seed was shipped to Montana.

Monitoring for Volunteer Plants: Nothing mentioned in report

Method of Devitalization or Final Disposition of Plot Area after Harvesting: Nothing mentioned in report.

Concerns: Where is this seed and what happened to it? Did anyone monitor this field for volunteers? What was the final disposition of the field?

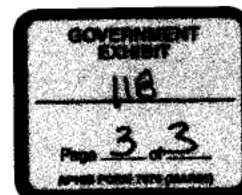
These examples are from just a few notifications that I reviewed. It does not appear in my opinion that Monsanto nor BRS did their due diligence in making sure that the protocols of these field test trials were met.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and that this declaration was executed on February 1, 2014.

(b) (6), (b) (7)(C)

Investigator
USDA-APHIS-IES

OR120018_BR_003714



(b) (6), (b) (7)(C) - APHIS

From: Juarez, Bernadette R - APHIS
Sent: Wednesday, July 03, 2013 12:45 PM
To: APHIS-IES RR Wheat
Subject: FW: APHIS contact at Ft. Collins
Attachments: Box details and shipping tracking numbers for (b)(6), (b) (7)(C).pdf; RR wheat sample transfer forms -may have duplicates.pdf; RR wheat sample transfer form.pdf; FW: GMO wheat seed questions

Follow Up Flag: Follow up
Due By: Monday, November 18, 2013 8:00 AM
Flag Status: Flagged

Just keeping you in the loop. I have attached my summary of the data as an FYI.

Bernadette Juarez, Deputy Director
Investigative and Enforcement Services
Animal and Plant Health Inspection Service U.S. Department of Agriculture
4700 River Road
Unit 85 (Room 6B-03B)
Riverdale, Maryland 20737
(301) 851-2735
(301) 734-4328 (facsimile)
bernadette.r.juarez@aphis.usda.gov

—Original Message—

From: (b) (6), (b) (7)(C)
Sent: Wednesday, July 03, 2013 11:32 AM
To: Juarez, Bernadette R - APHIS; Dierig, David
Cc: (b) (6), (b) (7)(C)
Subject: RE: APHIS contact at Ft. Collins

Good morning,

Per a request from Dr Dierig I have attached the files that I have scanned from our files regarding the Monsanto RR wheat. Upon receipt, the first box in the shipment was opened and the "Roundup Ready Wheat Sample Transfer Form" provided by the donor was photo-copied. The original was then replaced and the box was resealed. One donor (Sears) did not use the form and so the inventory sheet was scanned. No documentation was removed from the box received from Berg. The weights that are shown were provided from the individual donors.

In reviewing the scanned pdf files prior to sending, I noted that some of the cover sheets were duplicated between the two files but left the duplicates in as this is the way they are in the files.

Please contact me if you have any further questions.

(b) (6), (b) (7)(C)
USDA-ARS-NCGRP
1111 South Mason
Fort Collins, CO 80521-4500
tel # (b) (6), (b) (7)

OR120018_BR_003716



fax # 970.221.1427

mobile (b)(6), (b)(7)(C)

—Original Message—

From: Juarez, Bernadette R - APHIS

Sent: Wednesday, July 03, 2013 9:01 AM

To: Dierig, David

Cc: (b)(6), (b)(7)(C)

Subject: RE: APHIS contact at Ft. Collins

Thanks for the response. We look forward to the information from (b)(6)

Enjoy your time off.

B.

Bernadette Juarez, Deputy Director

Investigative and Enforcement Services

Animal and Plant Health Inspection Service U.S. Department of Agriculture

4700 River Road

Unit 85 (Room 6B-03B)

Riverdale, Maryland 20737

(301) 851-2735

(301) 734-4328 (facsimile)

bernadette.r.juarez@aphis.usda.gov

—Original Message—

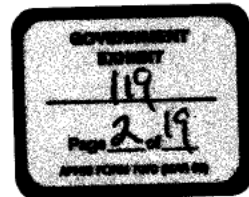
From: Dierig, David

Sent: Wednesday, July 03, 2013 10:50 AM

To: Juarez, Bernadette R - APHIS

Cc: (b)(6), (b)(7)(C)

Subject: Re: APHIS contact at Ft. Collins



Hi Bernadette

I'm out of the office until Monday but should be able help. We received the boxes from Monsanto in 2004. They were sealed and were never unsealed as verified by the two people here in charge of the intake and placement I to cold storage (and also incineration). We did weigh the boxes when they were received and the date of receipt to NCCGRP. I can get the spreadsheet scanned and sent to you by (b)(6), (b)(7)(C) who I've cced. Let me know if you need more info.

Thanks

Dave

Sent from my iPhone

On Jul 3, 2013, at 9:15 AM, "Juarez, Bernadette R - APHIS" <Bernadette.R.Juarez@aphis.usda.gov> wrote:

> Dr. Dierig –

>

> We have received a few additional questions involving the Monsanto seed sent to the ARS facility in Colorado. The questions involve the quantity of seed (or material) sent to ARS and the timeframe that the seed was held by

USDA. The records that I have on this matter were provided by Monsanto. See attached. APHIS does not have a way to verify the accuracy of these records, and, in any event, the records only reflect the number of "boxes" sent to ARS, not any specific quantity measures.

>
> Is this something with which you can assist? It would be best to rely on agency-held records to respond to this question. If ARS accepts material for storage by box rather than weight, that is fine. I am just not familiar with your routine business practices.

>
> Let me if there is anything I can do to help at our end.

>
> Thanks,

>
> B.

>
> Bernadette Juarez, Deputy Director
> Investigative and Enforcement Services Animal and Plant Health
> Inspection Service U.S. Department of Agriculture
> 4700 River Road
> Unit 85 (Room 6B-03B)
> Riverdale, Maryland 20737
> (301) 851-2735
> (301) 734-4328 (facsimile)
> bernadette.r.juarez@aphis.usda.gov

>
> —Original Message—

> From: (b) (6), (b) (7)
> Sent: Wednesday, June 26, 2013 3:15 PM
> To: Dierig, David
> Cc: (b) (6), (b) (7) Juarez, Bernadette R - APHIS
> Subject: APHIS contact at Ft. Collins

>
> Dave:

>
> Please provide the name of the APHIS employee that has the incinerator records and the name of a good contact at the agency who is working today.

>
> Bernadette Juarez, APHIS, here in DC is going to contact them directly - She is copied on this email.

>
> There is much urgency about confirming the incinerator.

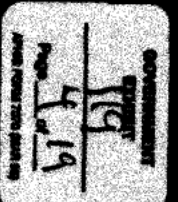
>
> (b) (6), (b) (7)

>
>
>
> <Monsanto glyphosate wheat 010512.xlsx> <document.pdf>



OR120018_BR_003722

Collection	ID	Date Received	Organization	Person	Address	Phone	Fax	Crop	# accessions	# boxes	Date sent to Inventor	Date induration confirmed
(b) (4)		1/11/2005	(b) (4)	(b) (4), (b) (6), (b) (7)(C)				riticum	304	1	12/12/2011	1/5/2012
		2/11/2005						riticum	304	2	12/12/2011	1/5/2012
		2/11/2005						riticum	304	3	12/12/2011	1/5/2012
		2/23/2005						riticum no list		1	12/12/2011	1/5/2012
		2/23/2005						riticum no list		2	12/12/2011	1/5/2012
		2/23/2005						riticum no list		3	12/12/2011	1/5/2012
		2/23/2005						riticum no list		4	12/12/2011	1/5/2012
		2/23/2005						riticum no list		5	12/12/2011	1/5/2012
		2/30/2004						riticum	37	1	12/12/2011	1/5/2012
		2/30/2004						riticum	37	2	12/12/2011	1/5/2012
		1/11/2005						riticum	486	1	12/12/2011	
		1/8/2005						riticum	52	1	11/14/2011	11/29/2011
		1/8/2005						riticum	52	2	11/14/2011	11/29/2011
		1/8/2005						riticum	52	3	11/14/2011	11/29/2011
		1/8/2005						riticum	52	4	11/14/2011	11/29/2011
		1/8/2005						riticum	52	5	11/30/2011	12/12/2011
		1/8/2005						riticum	52	6	11/30/2011	12/12/2011
		1/8/2005						riticum	52	7	11/30/2011	12/12/2011
		1/8/2005						riticum	52	8	11/30/2011	12/12/2011
		1/8/2005						riticum	52	9	11/30/2011	12/12/2011
		1/8/2005						riticum	52	10	11/30/2011	12/12/2011
		1/8/2005						riticum	52	11	11/30/2011	12/12/2011
		1/8/2005						riticum	52	12	11/30/2011	12/12/2011
		1/8/2005						riticum	52	13	11/30/2011	12/12/2011
		1/8/2005						riticum	52	14	11/30/2011	12/12/2011
		1/8/2005						riticum	52	15	11/30/2011	12/12/2011
		1/8/2005						riticum	52	16	11/30/2011	12/12/2011
		2/13/2004						riticum	18	1	10/18/2011	11/14/2011
		2/13/2004						riticum	18	2	10/18/2011	11/14/2011
		2/13/2004						riticum	18	3	10/18/2011	11/14/2011
		2/13/2004						riticum	18	4	10/18/2011	11/14/2011
		2/13/2004						riticum	18	5	11/14/2011	11/29/2011
		2/13/2004						riticum	18	6	11/14/2011	11/29/2011
		2/13/2004						riticum	18	7	11/14/2011	11/29/2011
		2/13/2004						riticum	18	8	11/14/2011	11/29/2011
		2/13/2004						riticum	18	9	11/14/2011	11/29/2011
		1/8/2005						riticum	58	1	12/12/2011	1/5/2012
		1/24/2005						riticum	3	1	12/12/11	1/5/2012
		12/28/2004						riticum	95	1	12/12/2011	1/5/2012
		12/14/2004						riticum no list		1	12/12/2011	1/5/2012
		12/14/2004						riticum no list		1	12/12/2011	1/5/2012
										1	12/12/2011	1/5/2012
										2	12/12/2011	1/5/2012



*Monsanto
wheat*

Name	City	State	# of Boxes	Tracking #	Rcvd
(b) (4)	(b) (4)	MO	2	846891051733	(all boxes) 4/5/2005
(b) (4)	(b) (4)	MO	9	5065016126	(all boxes) 12/13/2004
(b) (4)	(b) (4)	MN	16	1Z82Y83F 4290014211	(Box 1) 1/18/2005
				1Z82Y83F 4293385824	(Box 2)
				1Z82Y83F 0391070839	(Box 3)
				1Z82Y83F 4292665247	(Box 4)
				1Z82Y83F 4293005056	(Box 5)
				1Z82Y83F 4292766263	(Box 6)
				1Z82Y83F 4293064877	(Box 7)
				1Z82Y83F 4294056884	(Box 8)
				1Z82Y83F 4292538296	(Box 9)
				1Z82Y83F 4293545106	(Box 10)
				1Z82Y83F 4290953133	(Box 11)
				1Z82Y83F 4292078926	(Box 12)
				1Z82Y83F 4291277936	(Box 13)
				1Z82Y83F 4292546349	(Box 14)
				1Z82Y83F 4291120158	(Box 15)
				1Z82Y83F 4294075363	(Box 16)



1 large box
486 items

ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

(b) (6), (b) (7)(C)

SHIPPED BY: _____

SHIPPER FAX NUMBER: _____

(b) (6), (b) (7)(C)

DATE SHIPPED: _____

1-10-05

OF CONTAINERS SHIPPED: _____

1

AMOUNT SHIPPED (TOTAL BU OR LBS): _____

37[#]

RECEIVED BY: _____

(b) (6), (b) (7)(C)

DATE RECEIVED: _____

1-11-2005

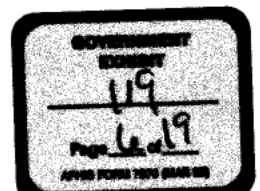
WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: _____

1

Receiver must fax completed form to (b) (6), (b) (7)(C) and the shipper. If any questions arise, call (b) (6), (b) (7)(C).



52 items

ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), (b) (7)(C) FAX # (b) (6), (b) (7)
OR E-MAIL (b) (6), (b) (7)(C)

DATE SHIPPED: Jan 19, 2005

OF CONTAINERS SHIPPED: 16

AMOUNT SHIPPED (TOTAL BU OR LBS): 645 lbs (gross wt)

VARIETY OR EXPERIMENTAL LINE: See attached inventory sheet

RECEIVED BY: (b) (6), (b) (7)(C)

DATE RECEIVED: 1-18-05

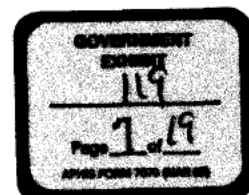
WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 16

Receiver must fax completed form to (b) (6), (b) (7)(C) and the shipper. If any questions arise, call (b) (6), (b) (7)(C)

OR120018_BR_003728



1 round white
plastic bin
3 samples

ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), (b) (7)(C)

SHIPPER FAX NUMBER: (b) (6), (b) (7)(C)

DATE SHIPPED: 21 January 2005

OF CONTAINERS SHIPPED: 1

AMOUNT SHIPPED (TOTAL BU OR LBS): 3 Kilograms

RECEIVED BY:

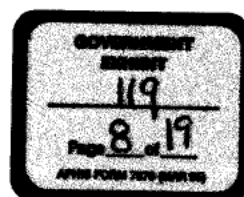
DATE RECEIVED: 1-24-05

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 1

Receiver must fax completed form to (b) (6), (b) (7)(C) and the shipper. If any questions arise, call (b) (6), (b) (7)(C).



1 small box
95 items

ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), (b) (7)(C)

SHIPPER FAX NUMBER: (b) (6), (b) (7)(C)

DATE SHIPPED: December 22, 2004

OF CONTAINERS SHIPPED: One

AMOUNT SHIPPED (TOTAL BU OR LBS): Total 2.5lbs, Seed Weight 0.8lbs

RECEIVED BY: _____

DATE RECEIVED: 12-28-2004

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 1

Receiver must fax completed form to (b) (6), (b) (7)(C) and the shipper. If any questions arise, call (b) (6), (b) (7)(C).

OR120018_BR_003732



2 boxes

no inventory list
enclosed

ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: [REDACTED] (b) (6), (b) (7)

SHIPPER FAX NUMBER: [REDACTED] (b) (4)

DATE SHIPPED: 12/14/04

OF CONTAINERS SHIPPED: 2

AMOUNT SHIPPED (TOTAL BU OR LBS): 44 pounds

RECEIVED BY: [REDACTED] (b) (6), (b) (7)(C)

DATE RECEIVED: 12-14-04

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 2

Receiver must fax completed form to [REDACTED] (b) (6), (b) (7)(C) and the shipper. If any questions arise, call [REDACTED] (b) (6), (b) (7)(C)).

OR120018_BR_003734



ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), (b) (7)(C)

SHIPPER FAX NUMBER: (b) (6), (b) (7)

DATE SHIPPED: 12/22/04

OF CONTAINERS SHIPPED: 2 boxes

AMOUNT SHIPPED (TOTAL BU OR LBS): 35lbs + 26lbs = 61 total lbs

5 bags: 1 x 5 kg hard white spring wheat; Soft white: 9 small bags (~ 200g each); Hard red: 11 small bags; Hard white: 8 small bags; and Club: 5 small bags.

RECEIVED BY: (b) (6), (b) (7)(C)

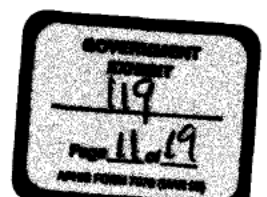
DATE RECEIVED: 12-30-2004

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 2

Receiver must fax completed form to (b) (6), (b) (7)(C) and the shipper. If any questions arise, call (b) (6), (b) (7)(C).



ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), (b) (7)(C)

SHIPPER FAX NUMBER: (b) (6), (b) (7)(C)

DATE SHIPPED: December 22, 2004

OF CONTAINERS SHIPPED: One

AMOUNT SHIPPED (TOTAL BU OR LBS): Total 2.5lbs, Seed Weight 0.8lbs

RECEIVED BY: (b) (6), (b) (7)(C)

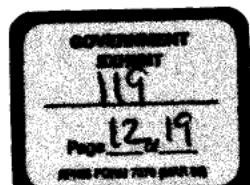
DATE RECEIVED: 12-28-2004

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 1

Receiver must fax completed form to (b) (6), (b) (7)(C) and the shipper. If any questions arise, call (b) (6), (b) (7)(C).



ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), (b) (7)(C)

SHIPPER FAX NUMBER: (b) (6), (b) (7)(C)

DATE SHIPPED: 21 January 2005

OF CONTAINERS SHIPPED: 1

AMOUNT SHIPPED (TOTAL BU OR LBS): 3 Kilograms

RECEIVED BY: (b) (6), (b) (7)(C)

DATE RECEIVED: 1-24-05

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 1

Receiver must fax completed form to (b) (6), (b) (7)(C) and the shipper. If any questions arise, call (b) (6), (b) (7)(C).

ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), [REDACTED] WestBred, LLC

SHIPPER FAX NUMBER: (b) (6), (b) (7)(C) [REDACTED]

DATE SHIPPED: February 9, 2005

OF CONTAINERS SHIPPED: 3

AMOUNT SHIPPED (TOTAL BU OR LBS): 100 lbs

RECEIVED BY: (b) (6), (b) (7)(C) [REDACTED]

DATE RECEIVED: 2-11-05

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 3

Receiver must fax completed form to (b) (6), (b) (7)(C) [REDACTED] and the shipper. If any questions arise, call (b) (6), (b) (7)(C) [REDACTED].



ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), (b) (7)(C)

DATE SHIPPED: 12/8/04

OF CONTAINERS SHIPPED: 9

AMOUNT SHIPPED (TOTAL BU OR LBS): 360 LBS

VARIETY OR EXPERIMENTAL LINES: ND758, ND759, ND763, ND764, ND 765, ND766, ND 768, ND769, ND 770, ND771, NDSW0247, NDSW0250, MNR01001, MNR01008, MNR02001, MNR02002, MNR02003, & SD0116

RECEIVED BY: (b) (6), (b) (7)(C)

DATE RECEIVED: 12-13-04

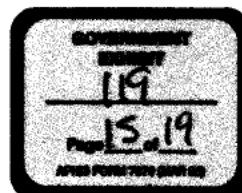
WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 9

Receiver must fax completed form to (b) (6), (b) (7) if any questions arise call (b) (6), (b) (7)(C)

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ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: [REDACTED] (b) (6), [REDACTED]

SHIPPER FAX NUMBER: [REDACTED] (b) (6), [REDACTED]

DATE SHIPPED: 12/14/04

OF CONTAINERS SHIPPED: 2

AMOUNT SHIPPED (TOTAL BU OR LBS): 44 pounds

RECEIVED BY: [REDACTED] (b) (6), (b) (7)(C)

DATE RECEIVED: 12-14-04

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 2

Receiver must fax completed form to [REDACTED] (b) (6), (b) (7)(C) and the shipper. If any questions arise, call [REDACTED] (b) (6), (b) (7)(C)).

ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: (b) (6), (b) (7)(C) FAX # (b) (6), (b) (7)
OR E-MAIL (b) (6), (b) (7)(C)

DATE SHIPPED: Jan 19, 2005

OF CONTAINERS SHIPPED: 16

AMOUNT SHIPPED (TOTAL BU OR LBS): 645 lbs (gross wt)

VARIETY OR EXPERIMENTAL LINE: See attached inventory sheet

RECEIVED BY: (b) (6), (b) (7)(C)

DATE RECEIVED: 1-18-05

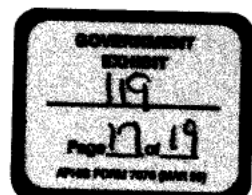
WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 16

Receiver must fax completed form to (b) (6), (b) (7)(C) and the
shipper. If any questions arise, call (b) (6), (b) (7)(C)

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(b) (4)

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ROUNDUP READY WHEAT SAMPLE TRANSFER FORM

(To be placed in the first box shipped of each shipment)

SHIPPED BY: [REDACTED] (b) (6), (b) (7) (C) [REDACTED]

SHIPPER FAX NUMBER: (b) (6), (b) (7) (C) [REDACTED]

DATE SHIPPED: 3/21/05

OF CONTAINERS SHIPPED: 5

AMOUNT SHIPPED (TOTAL BU OR LBS): 177 lbs.

RECEIVED BY: (b) (6), (b) (7) (C) [REDACTED]

DATE RECEIVED: 3-23-05

WAS THE SEED PROPERLY CONTAINED UPON RECEIPT: YES NO

IF NO EXPLAIN:

OF CONTAINERS RECEIVED: 5

Receiver must fax completed form to (b) (6), (b) (7) (C) [REDACTED] and the shipper. If any questions arise, call (b) (6), (b) (7) (C) [REDACTED].

(b) (6), (b) (7)(C) - APHIS

From: Coker, Richard S - APHIS
Sent: Thursday, July 25, 2013 1:47 PM
To: (b) (6), (b) (7) - APHIS
Cc: Juarez, Bernadette R - APHIS; Jhee, Edward M - APHIS; Abel, Sidney W - APHIS
Subject: For the Wheat Investigation File
Attachments: OR_Remedial_Action(b) (6), (b) (7) pdf

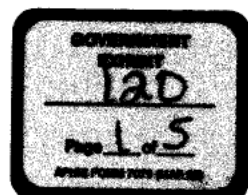
Hi (b) (6) - we sent the attached letter out to (b) (6), (b) (7) today. We also sent a copy to (b) (6), (b) (7). Passing along as I understand you're maintaining the investigation file.

Regards,
Rick

Rick Coker | Acting Chief of Staff BRS | Ofc. (301) 851-3939 | Cell (b) (6), (b) (7)(C)

NOTICE: This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

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Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

July 25, 2013

Re: APHIS' Order regarding the Mandatory Remedial Measures for (b) (6), (b) (7) Field

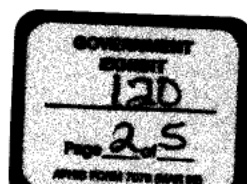
(b) (6), (b) (7) :

I write regarding the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service's (APHIS) ongoing investigation in connection with the detection of glyphosate resistant wheat volunteers on a (b)(6), (b)(7) that is leased and worked by your client (b) (6), (b) (7). At the outset, I wish to extend our gratitude regarding (b) (6), (b) (7) cooperation with this investigation and willingness to work with APHIS officials as we explore how these volunteers came to develop in his field, including his recent report that the wheat volunteers have, again, appeared in the field after its treatment with a combination of herbicides that included glyphosate.

USDA began an investigation into this matter on May 3, 2013, when an Oregon State University (OSU) scientist notified USDA officials that plant samples she received had tested positive for a transgene that made them resistant to glyphosate. APHIS confirmed OSU's results and determined that the genetic material was part of a specific "event" developed by Monsanto known as MON71800. Two separate USDA laboratories confirmed the identity of the genetic material. APHIS also used an independent laboratory to sequence a portion of the DNA found in the glyphosate resistant volunteers. APHIS analyzed the DNA sequence and found that it matched the DNA sequence for MON71800, which is a regulated, genetically engineered (GE) wheat that Monsanto developed. MON71800 has never been deregulated by APHIS and therefore MON71800 continues to be a regulated article subject to APHIS' regulatory authorities.

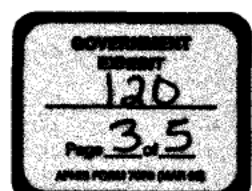
APHIS regulates the importation, interstate movement, and release into the environment of GE plants and organisms that are or might be plant pests under the Plant Protection Act (7 U.S.C. § 7701 et seq.) (PPA). The PPA provides APHIS with broad remedial authority to protect American agriculture from new plant pests, including GE plants that have not been deregulated. Specifically, section 7714 of the PPA provides APHIS with authority to issue an order to require remedial measures to prevent the dissemination of, among other things, a plant, plant product, or plant pest that has moved into or through the United States in violation of the PPA, including, for example, MON71800 and wheat plant tissue and seeds that may contain MON71800.

Pursuant to APHIS' regulatory authority under the PPA and after considering all of the known facts, evidence, test results, and recent detection of new volunteers, APHIS orders (b) (6), (b) (7)(C), as the person with control over the regulated GE wheat



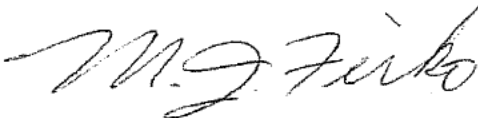
material, to take the following mandatory remedial actions that are necessary to effectively prevent the dissemination of regulated GE plant material:

- With respect to the (b)(6), (b)(7) where the regulated glyphosate resistant volunteers were detected (depicted in the center of the attached printout):
 - Effective immediately, no wheat material of any type (seed, plant material, plant parts, harvested grain) on or in the field may be removed, moved, treated, or otherwise destroyed without express authorization and permission of APHIS until the completion of the remedial actions described below.
 - No wheat may be planted in this field until APHIS confirms the effectiveness of the remedial actions described herein.
 - The field may be planted to a morphologically distinguishable crop beginning in the fall of 2013 (e.g., winter peas).
 - Regardless of whether the field remains fallow or a morphologically distinguishable crop is planted, the following remedial measures shall be taken:
 - A certified applicator shall apply fluazifop (Fusilade®) or sethoxydim (Poast®), or other herbicide that has similar properties and effect, to the entire (b)(6), (b)(7).
 - If any wheat volunteers are observed at any point, APHIS shall be notified by phone and the same herbicides shall be applied to wheat volunteers. The herbicide shall be applied to the wheat volunteers at the early seedling stage to maximize effectiveness.
 - APHIS must be notified within 7 days after each herbicide application, so that APHIS may conduct inspections to see if any wheat volunteers remain. If APHIS does detect any wheat volunteers, those volunteers are to be removed by mechanical or chemical means prior to flowering.
 - **Call the APHIS Compliance Hotline at 301-851-3935 within 7 days upon observance of any wheat volunteers and within 7 days after each herbicide application.**
 - APHIS must have access to the (b)(6), (b)(7) to monitor, inspect, and, as appropriate, sample plant material, until the agency has determined there is no risk of future wheat volunteers.



- (b)(6), (b)(7)(c) [REDACTED],
APHIS must have access to these fields to monitor, inspect, and sample harvested wheat material. APHIS will test the samples using the 35S quantitative polymerase chain reaction (PCR) assay. In the event any sample tests positive, APHIS will use a MON71800 event specific PCR assay to confirm the test result. In the event any wheat crop from either of the two fields is found positive for GE material, APHIS will determine and issue an order describing the mandatory remedial measures that will need to be implemented to effectively prevent the dissemination of any regulated GE plant material from the respective field or fields.
- (b)(6), (b)(7)(c) [REDACTED] APHIS must have access to these fields to monitor, inspect, and, as appropriate, sample plant material until further notice by APHIS.

If you have any questions regarding the mandatory remedial actions described above, please contact Mr. Richard Coker, Acting Chief of Staff for APHIS Biotechnology Regulatory Services (BRS), at (301) 851-3939, or e-mail at richard.s.coker@aphis.usda.gov. Again, we appreciate your willingness to cooperate with APHIS as we work to resolve this matter.



Michael J. Firko, Ph.D.
Deputy Administrator, Acting
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

(b) (6), (b) (7)(C)

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GOVERNMENT
EXHIBIT
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APHS FORM 7070 (MAY 89)

